

This binder provides you with summaries of selected publications on *Lactobacillus acidophilus* LA-5[®].

The publications are clinical studies performed in humans documenting the effects in various conditions.

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Chr. Hansen A/S
Human Health & Nutrition



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Research field: Gastrointestinal Health

Research subfield: Diarrhea

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 4 billion Product formulation: Capsules Reference number: 1326

Bhalla. Randomized placebo-controlled, double blind, Multicentric Trial on Efficacy and Safety of Providac techsules (Lactobacillus acidophilus LA-5 and Bifidobacterium BB -12) for prevention of Antibiotic-Associated Diarrhea in Indian patients. ACCP 2011; Chicago, Illinois:.

Abstract: Statement of Purpose, Innovation or Hypothesis: The role of probiotics in Antibiotic Associated Diarrhoea [AAD] has not been well studied. This trial evaluated the efficacy and safety of Providac techsules in the prevention of AAD in Indian patients. Description of Methods and Materials: Double blind placebo controlled multicentric trial with patients of either gender who require a systemic oral antibiotic therapy for 7 days were randomized into Providac or placebo treatment, taken twice daily after food for 14 days and followed up with symptom diary card for AAD assessment. Data and Results: Evaluable subjects, 176 in the Providac group while 167 in the placebo group, had comparable baseline profiles. After 14 days therapy, incidence of AAD in the Providac group was 10.8% compared to 15.56% in the placebo group(p=0.19). The duration of diarrhoea was significantly less (p=0.010) in the Providac group (2.32 \pm 2.31 days) compared to the placebo (4.58 \pm 3.08 days) group. Severe diarrhoea - (manifested as watery stool) was more in the Placebo group (96%) than the Providac group (31.6%) and this difference was highly significant statistically (p<0.0001). There were no Serious Adverse Events in any of the treatment arms and the adverse events which were observed were all non-serious, mild and self limiting. Interpretation, Conclusion or Significance: In Indian adult patients with AAD, Providac can effectively reduce the duration of diarrhea as well as its severity in terms of consistency of stools.



Research field: Immune Health
Research subfield: Inflammation
Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 2 billion

Product formulation: Fermented milk

Reference number: 1350

Asemi, et al. Effects of daily consumption of probiotic yoghurt on inflammatory factors in pregnant women: a randomized controlled trial Pak.J.Biol.Sci. 2011;14(8):476-482

Abstract: Previous studies have shown that inflammatory factors increases in pregnancy and is associated with several complications of pregnancy. The aim of this study was to assess effects of daily consumption of probiotic yoghurt on inflammatory factors in pregnant women. In a randomized clinical trial, seventy primigravid (the first pregnancy) and singleton pregnant women aged 18-30 years were assigned to two groups. Subjects consumed daily 200 g probiotic yoghurt containing Lactobacillus acidophilus La5 and Bifidobacterium animalis BB12 (10(7) CFU q(-1) for each) or 200 q conventional yoghurt for 9 weeks. Fasting blood samples were collected at baseline (28 weeks of gestation) and after intervention (37 weeks of gestation). Inflammatory factors, hs-CRP and TNF-alpha, were measured by Enzyme-linked Immunosorbent Assay (ELISA). Independent t-test was used to compare the two groups after intervention and paired-sample t-test compared variables before and after treatment. The results showed that the probiotic yogurt brought about a decrease in the serum hs-CRP level, from 10.44 +/- 1.56 to 7.44 +/- 1.03 microg mL(-1) (p = 0.041). There was no significant change in the conventional yogurt group in the serum hs-CRP level (12.55 +/- 1.57 to 14.51 +/- 1.62 microg mL(-1), p = 0.202). The probiotic yogurt had no effect on TNF-alpha (from 73.75 +/- 6.59 to 77.91 +/- 5.61 pg mL(-1), p = 0.633). Serum TNF-alpha did not change in the conventional yogurt group (p = 0.134). In conclusion probiotic yogurt significantly decreased hs-CRP in pregnant women but had no effect on TNF-alpha.



Research field: Gastrointestinal Health

Research subfield: Diarrhea

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 0.25 billion
Product formulation: Fermented milk

Reference number: 1345

de Vrese, et al. Probiotic lactobacilli and bifidobacteria in a fermented milk product with added fruit preparation reduce antibiotic associated diarrhea and Helicobacter pylori activity J.Dairy Res. 2011:1-8

Abstract: To investigate matrix-specifity of probiotic effects and particularly of the reduction of antibiotics-associated diarrhea, a controlled, randomized, double-blind study was performed, in which 88 Helicobacter pylori-infected but otherwise healthy subjects were given for eight weeks either a) a probiotic fruit yoghurt "mild" containing Lactobacillus acidophilus LA-5 plus Bifidobacterium lactis BB-12, n=30), b) the same product but pasteurized after fermentation (n=29) or c) milk acidified with lactic acid (control, n=29). During week five, a Helicobacter eradication therapy was performed. Helicobacter activity was measured via 13C-2-urea breath tests and antibiotic-associated diarrhoea and other gastrointestinal complaints were recorded by validated questionnaires. In intervention group a, b and c the mean number of days with diarrhoea was 4, 10 and 10 (P<0.05), the frequency of episodes 17%, 7% and 27% (n.s.), and the change in total symptoms score before antibiotics treatment was -1.4 ± 1.1 , -1.2 ± 1.1 , 2.6 ± 1.1 points/four weeks (P<0.05). All milk products decreased Helicobacter activity by 18 to 45% without significant differences between groups. The observed decrease in Hel. pylori activity seems to be not or not only due to probiotic bacteria but (rather) to components of acidified milk (most probably lactic acid). Fruit-yogurt-like fermented milk products with living probiotic bacteria significantly shorten the duration of antibiotics-associated diarrhoea and improve gastrointestinal complaints. Fruit yogurt-like fermented milk is a matrix suitable for probiotic bacteria.



Research field: CVD markers
Research subfield: Cholesterol
Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: NA

Product formulation: Fermented milk

Reference number: 1320

Ejtahed, et al. Effect of probiotic yogurt containing Lactobacillus acidophilus and Bifidobacterium lactis on lipid profile in individuals with type 2 diabetes mellitus. J.Dairy Sci. 2011;94:3288-3294

Abstract: The purpose of this study was to investigate the effects of probiotic and conventional yogurt on the lipid profile in type 2 diabetic people. In a randomized double-blind controlled trial, 60 people (23 males and 37 females) with type 2 diabetes and low-density lipoprotein cholesterol (LDL-C) greater than 2.6 mmol/L were assigned to 2 groups. Participants consumed daily 300g of probiotic yogurt containing Lactobacillus acidophilus La5 and Bifidobacterium lactis Bb12 or 300g of conventional yogurt for 6 wk. Fasting blood samples, anthropometric measurements and 3-d, 24-h dietary recalls were collected at the baseline and at the end of the trial. Probiotic yogurt consumption caused a 4.54% decrease in total cholesterol and a 7.45% decrease in LDL-C compared with the control group. No significant changes from baseline were shown in triglyceride and high-density lipoprotein cholesterol (HDL-C) in the probiotic group. The total cholesterol:HDL-C ratio and LDL-C:HDL-C ratio as atherogenic indices significantly decreased in the probiotic group compared with the control group. Probiotic yogurt improved total cholesterol and LDL-C concentrations in type 2 diabetic people and may contribute to the improvement of cardiovascular disease risk factors.



Research field: Gastrointestinal Health and Immune Health **Research subfield:** Irregular bowel movements / Inflammation

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 2.4 billion Capsules Reference number: 1294

Nova, et al. Beneficial effects of a synbiotic supplement on self-perceived gastrointestinal well-being and immunoinflammatory status of healthy adults. J.Med.Food 2011;14:79-85

Abstract: Abstract The use of synbiotics as health promoters is still poorly defined, and human intervention studies are scarce. This study was designed to evaluate the effects of a commercialized synbiotic product containing Lactobacillus acidophilus La5, Bifidobacterium animalis ssp. lactis Bb-12, Lactobacillus delbrueckii ssp. bulgaricus, Lactobacillus paracasei ssp. paracasei, Streptococcus thermophilus, and fructooligosaccharides on the self-reported gastrointestinal well-being and the immunoinflammatory status of healthy human subjects. In this randomized, double-blind, placebo-controlled study, 20 women and 16 men (25-45 years old) received either three tablets per day of the synbiotic product (2.4 x 10(9) colony-forming units/day) or placebo during 6 weeks. Gastrointestinal symptoms and bowel habits were evaluated through a self-administered questionnaire. In those subjects suffering from any kind of digestive disturbance (mild dyspepsia, flatulence, postprandial bloating, constipation, etc.), improvements in symptoms after product consumption were also evaluated. Blood lymphocyte subsets, phagocytic activity, serum C-reactive protein, ceruloplasmin, and adhesion molecules concentrations were analyzed prior and after treatment. A significant improvement in overall self-reported gastrointestinal symptoms and bowel habit was found in the symbiotic group. A marginal effect of treatment (analysis of variance P = .050) was observed with L-selectin, which showed a significant decrease in the synbiotic group (P = .019). In addition, basal L-selectin levels correlated with final intercellular adhesion molecule (ICAM)-1 levels (r = 0.468; P = .050), and basal ICAM-1 levels tended to correlate negatively with final L-selectin concentration (r = -0.457; P = .056). None of these correlations was found in the placebo group. The rest of the immunological parameters studied were not modified by the intervention. In conclusion, consumption of the synbiotic product improves self-perceived bowel habits and might facilitate a better profile of adhesion molecules in healthy adults.



Research field: Gastrointestinal Health

Research subfield: Microbiota
Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 1 billion LA-5 + 1 or 10 billion BB-12

Product formulation: Fermented milk

Reference number: 1296

Savard, et al. Impact of Bifidobacterium animalis subsp. lactis BB-12 and, Lactobacillus acidophilus LA-5-containing yoghurt, on fecal bacterial counts of healthy adults. Int.J.Food Microbiol. 2011:.

Abstract: This randomized, placebo-controlled, double blind, parallel dose-response study investigated the impact of 4-week commercial yoghurt consumption supplemented with Bifidobacterium animalis subsp. lactis (BB-12) and Lactobacillus acidophilus (LA-5) on fecal bacterial counts of healthy adults. Fifty-eight volunteers were randomly assigned to three different groups: 1. placebo (no probiotic, no starter and no green tea extract); 2. Yoptimal (10(9)cfu/100g of BB-12 and LA-5 and 40mg of green tea extract) and 3. Yoptimal-10 (10(10)cfu/100g of BB-12, 10(9)cfu/100g of LA-5 and 40mg of green tea extract). These yoghurt products also contained Lactobacillus delbrueckii subsp. bulgaricus (10(7)cfu/100q) and Streptococcus thermophilus (10(10)cfu/100q). The quantitative PCR (qPCR) results showed that there were significant increases (P=0.02) in bifidobacteria counts with the Yoptimal treatment as compared to baseline. The fecal numbers of B. animalis subsp. lactis and LA-5 significantly increased in the two probiotic treatments compared to the placebo treatment. Viable counts of fecal lactobacilli were significantly higher (P=0.05) and those of enterococci were significantly lower (P=0.04) after the intervention when compared to placebo. No significant difference was observed between treatments in volunteers' weight, waist girth, blood pressure, fasting plasma triglyceride and HDL-C concentrations, as well as cholesterol/HDL-cholesterol ratio. However, a significant increase in plasma cholesterol levels was observed in the placebo group (P=0.0018) but the levels remained stable in the two probiotic voghurt groups. These results show that probiotic strains supplemented in the form of yoghurt remain active during gut transit and are associated with an increase in beneficial bacteria and a reduction in potentially pathogenic bacteria. This trial was registered at clinicaltrials.gov as NCT00730626.



Research field: Other
Research subfield: Oral health
Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 0.1 billion Product formulation: Other Reference number: 1304

Singh, et al. Salivary mutans streptococci and lactobacilli modulations in young children on consumption of probiotic ice-cream containing Bifidobacterium lactis Bb12 and Lactobacillus acidophilus La5. Acta Odontol.Scand. 2011:.

Abstract: Abstract Objectives. To compare the levels of mutans streptococci and lactobacilli in saliva of school children, before and after consumption of probiotic and control ice-cream. Materials and methods. A double-blind, cross-over, placebo-controlled trial was carried out in forty, 12-14 year-old children, with no clinically detectable caries. The selected children were randomized equally into two groups I and II. Following an initial run-in period of 1 week, children in group I and II were given ice-creams 'A' and 'B', respectively, for 10 days. Being a cross-over study, the ice-creams were interchanged in the two groups after a 2-week wash-out period. Saliva samples at baseline and follow-up were assessed using Dentocult SM and Dentocult LB kits. Results. On statistical evaluation, it was seen that probiotic ice-cream brought about a statistically significant reduction (p-value = 0.003) in salivary mutans streptococci levels with no significant effect on lactobacilli levels. Conclusion. In conclusion, probiotic ice-cream containing Bifidobacterium lactis Bb-12 ATCC27536 and Lactobacillus acidophilus La-5 can reduce the levels of certain caries-associated microorganisms in saliva.



Research field: Immune Health
Research subfield: Atopic diseases
Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5 and L. rhamnosus LGG

Dosage CFU/day: 1 billion LA-5 + 10 billion BB-12 and LGG each

Product formulation: Fermented milk

Reference number: 0855

Dotterud, et al. Probiotics in pregnant women to prevent allergic disease: a randomized, double-blind trial. Br.J.Dermatol. 2010;163:.

Abstract: Summary Background Previous reports have suggested that certain probiotics given to mothers and children at risk of atopy halves the incidence of atopic dermatitis (AD) at 2 years of age. Objectives To examine if probiotics given to pregnant women in a nonselected population could prevent atopic sensitization or allergic diseases during the child's first 2 years. Methods In a randomized, double-blind trial of children from a nonselected maternal population (ClinicalTrials.gov identifier: NCT00159523), women received probiotic milk or placebo from 36 weeks of gestation to 3 months postnatally during breastfeeding. The probiotic milk contained Lactobacillus rhamnosus GG, L. acidophilus La-5 and Bifidobacterium animalis subsp. lactis Bb-12. Children with an itchy rash for more than 4 weeks were assessed for AD. At 2 years of age, all children were assessed for atopic sensitization, AD, asthma and allergic rhinoconjunctivitis. The intention-totreat (ITT) analysis was enabled by multiple imputations. Results Four hundred and fifteen pregnant women were computer randomized. At 2 years, 138 and 140 children in the probiotic and the placebo groups, respectively, were assessed. In the ITT analysis, the odds ratio (OR) for the cumulative incidence of AD was 0.51 in the probiotic group compared with the placebo [95% confidence interval (CI) 0.30-0.87; P = 0.013]. There were no significant effects on asthma (OR 0.68, 95% CI 0.26-1.80; P = 0.437) or atopic sensitization (OR 1.52, 95% CI 0.74-3.14; P = 0.254). Conclusions Probiotics given to nonselected mothers reduced the cumulative incidence of AD, but had no effect on atopic sensitization.



Research field: Gastrointestinal Health

Research subfield: Diarrhea

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5 and L. rhamnosus LGG

Dosage CFU/day: 25 billion LGG, 2.5 billion LA-5, 25 billion BB-12

Product formulation: Fermented milk

Reference number: 0627

Wenus, et al. Prevention of antibiotic-associated diarrhoea by a fermented probiotic milk drink. Eur.J.Clin.Nutr. 2008;62:299-301

Abstract: OBJECTIVE: To study the preventive effect of a milk drink fermented with multistrain probiotics on antibiotic associated diarrhoea (AAD). DESIGN: Double-blind placebo controlled study. SETTING: University Hospital of North Norway. SUBJECTS AND METHODS: Of 853 patients treated with antibiotics, 87 met the inclusion criteria, and were randomized to ingestion of a fermented milk drink containing LGG, La-5 and Bb-12 (n=46) or placebo with heat-killed bacteria (n=41), during a period of 14 days. A diary was recorded, and stool samples were collected for microbiological analyses. RESULTS: Sixty-three patients completed the study according to the protocol; two patients (5.9%) in the treatment group and eight (27.6%) in the placebo group developed AAD (P=0.035). The relative risk of developing AAD was 0.21 (95% confidence interval: 0.05-0.93) when given probiotic milk drink. CONCLUSION: A fermented multistrain probiotic milk drink may prevent four of five cases of AAD in adult hospitalized patients. SPONSORSHIP: TINE BA, Oslo, Norway.



Research field: Gastrointestinal Health

Research subfield: Diarrhea

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: > 400 billion of each bacteria

Product formulation: Fermented milk

Reference number: 0508

Sheu, et al. Pretreatment with Lactobacillus- and Bifidobacterium-containing yogurt can improve the efficacy of quadruple therapy in eradicating residual Helicobacter pylori infection after failed triple therapy. Am.J.Clin.Nutr. 2006;83:864-869

Abstract: Background: Lactobacillus- and Bifidobacterium-containing yogurt (AB-yogurt) can suppress Helicobacter pylori. Improvement of the eradication rate by quadruple therapy of residual H. pylori after failed triple therapy is needed. /// Objective: We tested whether prior treatment with AB-yogurt improved the efficacy of quadruple therapy in eradicating residual H. pylori after failed triple therapy. /// Design: One hundred thirty-eight patients in whom triple therapy failed were enrolled for a culture study of H. pylori to assess antimicrobial resistance. These patients were then randomly assigned in equal numbers to either a yogurt-plus-quadruple therapy group or a quadruple therapy-only group. The patients received 1 wk of quadruple therapy with or without a 4-wk pretreatment with AB-yogurt (400 mL/d). In the yogurt-plusquadruple group, excessive δ13CO2/mL values of the 13C-urea breath test were collected before and every 2 wk during the 4-wk ingestion of yogurt. For both groups, a 13C-urea breath test was conducted >6 wk after the quadruple therapy to assess the outcome of residual H. pylori eradication. /// Results: For the patients in the yogurt-plus-quadruple therapy group infected with either antibiotic-sensitive or -resistant H. pylori, the excessive δ13CO2/mL values of the 13C-urea breath test were significantly decreased after the 4-wk ingestion of AB-yogurt (P < 0.0001). The yogurt-plus-quadruple therapy group had a higher H. pylori eradication rate than did the quadruple therapy-only group (intention-to-treat analysis: 85% compared with 71.1%, P < 0.05; per-protocol analysis: 90.8% compared with 76.6%, P < 0.05). /// Conclusion: A 4-wk pretreatment with AB-yogurt can decrease H. pylori loads despite antimicrobial resistance, thus improving the efficacy of quadruple therapy in eradicating residual H. pylori.



Research field: Gastrointestinal Health

Research subfield: Diarrhea

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 40 billion Product formulation: Capsules Reference number: 0499

Wildt, et al. Probiotic treatment of collagenous colitis: a randomized, double-blind, placebo-controlled trial with Lactobacillus acidophilus and Bifidobacterium animalis subsp. Lactis. Inflamm.Bowel Dis. 2006;12:395-401

Abstract: BACKGROUND: Probiotic treatment may be effective in diseases involving gut microflora and intestinal inflammation. In collagenous colitis (CC), a potential pathogenic role of the gut microflora has been proposed. The effect of probiotic treatment in CC is unknown. Our aim was to investigate the clinical effect of treatment with Lactobacillus acidophilus LA-5 and Bifidobacterium animalis subsp. lactis BB-12 (AB-Cap-10) in patients with CC. MATERIALS AND METHODS: Patients with CC and diarrhea were in a double-blind placebo-controlled study randomized (2:1) to AB-Cap-10 or placebo for 12 weeks. The primary end point was reduction in bowel frequency per week of >or=50%. Secondary end points were changes in bowel frequencies, stool consistency, stool weight, histopathology, and abdominal bloating and pain. RESULTS: Twenty-nine patients were randomized: 21 to probiotics and 8 to placebo. Reduction in bowel frequency per week of >or=50% occurred in 6 of 21 (29%) and in 1 of 8 (13%) patients receiving probiotic and placebo, respectively (P = 0.635). No differences between treatments were observed regarding the secondary end points. Post hoc analysis showed a median reduction in bowel frequency per week from 32 (range 18-84) to 23 (range 11-56; P < 0.005), a reduction in number of days with liquid stools per week from 6 days (range 0-7 days) to 1 day (range 0-7 days; P < 0.005), and an increase in number of days with solid stools per week (P < 0.05) in the AB-Cap-10 group. CONCLUSIONS: AB-Cap-10 had no significant effect on the chosen end points. Post hoc analysis demonstrated amelioration of clinical symptoms in the AB-Cap-10 group, indicating that probiotic treatment may potentially influence the disease course of CC.



Research field: Gastrointestinal Health

Research subfield: Other

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 50 billion Product formulation: Fermented milk

Product formulation: Ferme Reference number: 0473

Laake, et al. Outcome of four weeks' intervention with probiotics on symptoms and endoscopic appearance after surgical reconstruction with a J-configurated ileal-pouch-anal-anastomosis in ulcerative colitis. Scand.J.Gastroenterol. 2005;40:43-51

Abstract: OBJECTIVE: Pouchitis is a common and troublesome condition in patients operated on with ilealpouch-anal-anastomosis (IPAA). A disturbed microecology in the pouch has been suggested as one possible explanation. In a previous double-blind, randomized, controlled study we demonstrated clinical improvement of symptoms in patients with ulcerative colitis (UC) operated on with IPAA, during intervention with live probiotic microbes Lactobacilli and Bifidobacteriae. The aim of the present study was to confirm our previous results in a much larger material, including clinical symptoms, faecal flora and endoscopic evaluation, and to compare the results in UC/IPAA patients with those of patients with familial adenomatous polyposis (FAP) with IPAA and UC patients with ileorectal anastomosis (IRA). MATERIAL AND METHODS: Five hundred millilitres of a fermented milk product (Cultura) containing live lactobacilli (La-5) and bifidobacteriae (Bb-12) was given daily for 4 weeks to 51 UC patients and 10 patients with FAP, operated on with IPAA, and six UC patients operated on for IRA. Stool samples were cultured for examination of lactobacilli, bifidobacteriae, fungi and pH before, during and after intervention. Before, during and after intervention, endoscopic evaluation was performed. Categorized symptomatology was examined prospectively using diary cards in addition to an interview, before and on the last day of intervention. RESULTS: The number of lactobacilli and bifidobacteriae increased significantly during intervention in the UC patients operated on with IPAA and remained significantly increased one week after intervention. Involuntary defecation, leakage, abdominal cramps and the need for napkins (category I), faecal number and consistency (category II) and mucus and urge to evacuate stools (category III) were significantly decreased during intervention in the UC/IPAA group. In the FAP group there was a significant decrease in faecal leakage, abdominal cramps and use of napkins (category I) during intervention. The median endoscopic score of inflammation was significantly decreased during intervention in the UC/IPAA patients. Blood tests, faecal fungi and faecal pH did not change significantly during intervention. CONCLUSIONS: Results of this extended study, showing an effect of probiotics on symptoms and endoscopic inflammation in UC patients operated on with IPAA confirm our previously reported effect of probiotics on clinical symptoms and endoscopic score in a smaller, double-blind, randomized, controlled study. The significantly higher response to probiotics in families with increased risk of IBD will have to be repeated in future studies.



Research field: Gastrointestinal Health **Research subfield:** Inflammatory bowel disease

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: Approx. 50 billion of each bacteria

Product formulation: Fermented milk

Reference number: 0466

Laake, et al. Assessment of mucosal inflammation and blood flow in response to four weeks' intervention with probiotics in patients operated with a J-configurated ileal-pouch-anal-anastomosis (IPAA). Scand.J.Gastroenterol. 2004;39(12):1228-1235

Abstract: BACKGROUND: Pouchitis is a common and troublesome condition in patients operated on with ileal-pouch-anal-anastomosis (IPAA). A disturbed mucosal perfusion in the pouch has been suggested as a possible cause. Laser Doppler flowmetry (LDF) has been used successfully to measure gastric and colonic mucosal perfusion in humans. In a previous study, we demonstrated a reduced mucosal perfusion in the distal part of the pouch, during probiotic intervention, examined by LDF measurement. The aim of the present study was to confirm our previous results in a much larger material, and to compare the results of LDF measurements and inflammatory activity in ulcerative colitis (UC) patients with those in familial adenomatous polyposis (FAP) patients. METHODS: Five hundred millilitres of a fermented milk product (Cultura), containing live lactobacilli (La-5) and bifidobacteria (Bb-12), was given daily for 4 weeks to 41 UC and 10 patients with FAP, operated on with IPAA. Mucosal perfusion was measured with LDF and the degree of inflammation was examined at predefined levels of the distal bowel by histology and faecal calprotectin measurements both before and after intervention. We also evaluated the applicability of a Pouchitis Disease Activity Index (PDAI). RESULTS: The LDF measurements were reproducible in the pelvic pouch at each of the predefined levels, but did not change during intervention. Mucosal perfusion was significantly reduced in the distal compared to the proximal part of the pouch in the UC group (P < 0.05). The perfusion levels were higher in the FAP patients compared to the UC patients at all predefined levels (P < 0.05). Calprotectin levels and histological score did not change significantly after intervention in any of the groups. The calprotectin level was significantly lower in the FAP compared to the UC group both before and after intervention. The PDAI decreased in both groups from alevel considered diagnostic for pouchitis to a level considered as not active pouchitis. The decreasewas significant for the UC patients. CONCLUSIONS: The results did not demonstrate an effect of probiotics on histology, although a significant effect on the PDAI was achieved, which concurs with the previously reported effect on symptoms and endoscopic score. The significantly reduced blood flow in the UC group compared to the FAP group, operated on with the same procedure, and the significantly increased calprotectin levels in the UC group, are original findings. Both findings may be related to an increased risk for pouchitis among UC patients. The lack of effect of intervention on mucosal perfusion does not exclude a role for reduced circulation as a cause of pouchitis based on the reduced LDF measurements in the distal part of the pouch.



Research field: Gastrointestinal Health

Research subfield: Diarrhea

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: > 4.6 billion **Product formulation:** Fermented milk

Reference number: 0447

Wang, et al. Effects of ingesting Lactobacillus- and Bifidobacterium-containing yogurt in subjects with colonized Helicobacter pylori. Am.J.Clin.Nutr. 2004;80:737-741

Abstract: Background: Evidence suggests that ingesting lactic acid bacteria exerts a suppressive effect on Helicobacter pylori infection in both animals and humans. Supplementing with Lactobacillus- and Bifidobacterium-containing yogurt (AB-yogurt) was shown to improve the rates of eradication of H. pylori in humans. /// Objective: We administered AB-yogurt to subjects with asymptomatic H. pylori to test whether the yogurt could inhibit H. pylori growth. /// Design: The in vitro inhibition of H. pylori growth was determined by inoculating Lactobacillus acidophilus La5 or Bifidobacterium lactis Bb12 on plates that were inoculated with H. pylori. Assessment of the viability of H. pylori was performed by the mixed culture method with La5 or Bb12. In an intervention study, 59 adult volunteers infected with H. pylori were given AB-yogurt (107 colony-forming units of both La5 and Bb12/mL) twice daily after a meal for 6 wk. Eleven subjects positive for H. pylori infection were treated with milk placebo as control subjects. H. pylori bacterial loads were determined with use of the 13C-urea breath test, which was performed before and 4 and 8 wk after the start of AB-yogurt supplementation. /// Results: Bb12 exerted an in vitro inhibitory effect against H. pylori, whereas La5 did not show an effect. Administration of AB-yogurt decreased the urease activity of H. pylori after 6 wk of therapy (P < 0.0001). /// Conclusion: Regular intake of yogurt containing Bb12 and La5 effectively suppressed H. pylori infection in humans.



Research field: Gastrointestinal Health

Research subfield: Inflammatory bowel disease / Microbiota

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 50 billion

Product formulation: Fermented milk

Reference number: 0420

Laake, et al. Assessment of mucosal inflammation and circulation in response to probiotics in patients operated with ileal pouch anal anastomosis for ulcerative colitis. Scand.J.Gastroenterol. 2003;38:409-414

Abstract: BACKGROUND: Pouchitis is a common and troublesome condition, and a disturbed microbiological flora and mucosal blood flow in the pouch have been suggested as possible causes. Laser Doppler flowmetry (LDF) has been used successfully to measure gastric and colonic mucosal perfusion in humans. The aim of this study was to evaluate the effect of intervention with probiotics on ileal pouch inflammation and perfusion in the pouch, assessed by endoscopy, histology, fecal calprotectin and LDF. METHODS: A fermented milk product (Cultura; 500 ml) containing live lactobacilli (La-5) and bifidobacteria (Bb-12) was given daily for 4 weeks to 10 patients operated with ileal-pouch-anal anastomosis (IPAA) for ulcerative colitis (UC). Mucosal perfusion was measured with LDF and the degree of inflammation was examined at predefined levels of the distal bowel by endoscopy and histology. Stool samples were cultured for lactobacilli and bifidobacteria and calprotectin were measured before and after intervention. RESULTS: The LDF measurements were reproducible in the pelvic pouch at each of the predefined levels, but did not change after intervention. The mucosal perfusion was reduced in the distal compared to the proximal part of the pouch. Calprotectin levels did not change significantly after intervention. The median endoscopic score for inflammation was significantly reduced by 50% after intervention, whereas the histological score did not change significantly. CONCLUSION: The results suggest that probiotics primarily act superficially, with change of gross appearance of the mucosa at endoscopy, but without significant effect on histological picture, mucosal perfusion or faecal calprotectin, during a relatively short period of 4 weeks.



Research field: Gastrointestinal Health

Research subfield: Diarrhea

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: > 10 billion
Product formulation: Fermented milk

Reference number: 0412

Sheu, et al. Impact of supplement with Lactobacillus- and Bifidobacterium-containing yogurt on triple therapy for Helicobacter pylori eradication. Aliment.Pharmacol.Ther. 2002;16:1669-1675

Abstract: Aim: To test whether supplements of Lactobacillus- and Bifidobacterium-containing yogurt (AB-Yogurt) affect the success of Helicobacter pylori eradication. /// Methods: One hundred and sixty H. pylori-infected patients were randomized into a triple-plus-yogurt group or a triple-only group, receiving 1 week of triple therapy with and without supplements of AB-Yogurt, respectively. In the triple-plus-yogurt group, AB-Yogurt was continued for 4 weeks after triple therapy. Eight weeks later, patients were assessed for the success of H. pylori eradication. The stool samples of 22 randomly selected patients, 11 from each group, were provided on enrolment, at the first week and at the fifth week for evaluation of the percentage of Bifidobacterium in anaerobes. /// Results: By intention-to-treat analysis, the triple-plus-yogurt group had a higher H. pylori eradication rate than the triple-only group (91% vs. 78%, P < 0.05). The per protocol H. pylori eradication rates were similar for both groups (93.5% vs. 89%, P = N.S.). Only patients supplemented with AB-Yogurt showed restoration of the percentage of Bifidobacterium in the anaerobes of stools at the fifth week to the level in the stools on enrolment. /// Conclusions: Supplement with AB-Yogurt can improve the intention-to-treat eradication rates of H. pylori, and can restore the depletion of Bifidobacterium in stools after triple therapy.



Research field: Gastrointestinal Health
Research subfield: Irregular bowel movements

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 1 billion BB-12 and 0.3 billion LA-5

Product formulation: Fermented milk

Reference number: 0531

Shioya, et al. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora and fecal properties in healthy female volunteers. Food Health and Nutrition Research (Journal of Nutritional Food) 2000:18-18

Abstract: DESIGN: In a crossover study, 46 healthy female volunteers with the average age of 19.7 y were given 100 mL/d of fermented milk containing Bifidobacterium lactis FK 120 (BB-12, Lactobacillus acidophilus FK 205 (LA-5), Streptococcus thermophilus FK 303 (TH-3) and Sterptococcus thermophilus FK 320 (ST-20) and 100 mL/d of pure milk as placebo for up to ten days in order to examine the effect on fecal properties and defecation frequencies. The fecal microflora, pH, water content and ammonia concentration were also examined in 10 subjects (mean age 19.8 y). RESULTS: When comparing the BB-12 period with the placebo period, BB-12 was effective in increasing the fecal amount and in changing the fecal properties positively. The ratio of bifidobacteria to total bacteria was increased, and the frequency of Clostridium prefringens was decreased, as was the fecal pH. There was a tendency towards a decreased ammonia concentration and towards increased water content. It should be noted that the authors only highlight BB-12.



Research field: Gastrointestinal Health
Research subfield: Irregular bowel movements

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 1 billion BB-12 and 0.3 billion LA-5 or 3 billion BB-12 and 0.9 billion LA-5

Product formulation: Fermented milk

Reference number: 0530

Shioya, et al. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora, with special reference to Bifidum species, and fecal properties in healthy volunteers. Food Health and Nutrition Research (Journal of Nutritional Food) 2000:19-32

Abstract: DESIGN: The effects of Bifidobacterium lactis FK 120 (BB-12), Lactobacillus acidophilus FK 320 (LA-5), Streptococcus thermophilus FK 303 (TH-3) and Streptococcus thermophilus FK 320 (ST20) on fecal properties and defecation frequency were examined in 48 healthy, volunteers with the average age of 42.0 y, who were given 100 mL/d or 300 mL/d of fermented milk containing BB-12 for two weeks. Additionally, the effect of BB-12 on the composition of Bifidobacterium species in fecal microflora and on fecal properties were examined in 7 volunteers with the average age of 45.7 y. RESULTS: The intake of fermented milk containing BB-12 improved the fecal flora without a change in the composition of Bifidobacterium species. During the intake period, increase in defecation frequency and fecal amount, and improvement of fecal shape and coloring were observed. The ratio of Bifidobacteria to total bacteria was increased by the intake. The frequency of C. perfringes and Clostridium-others as well as fecal ammonia (P<0.01) was decreased by the intake. BB-12 was detected in the feces of four volunteers during the BB-12 administration with 107.3-8.8 cfu/g. In the composition of fecal Bifidobacterium species, the high incidence if B. adolescentis and B. longum were observed throughout the experimental periods. It should be noted that the authors only highlight BB-12.



Research field: Gastrointestinal Health
Research subfield: Irregular bowel movements

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 1 billion BB-12 and 0.3 billion LA-5

Product formulation: Fermented milk

Reference number: 0532

Shioya, et al. Effect of fermented milk containing Bifidobacterium lactis FK 120 on the fecal flora, with special reference to Bifidum species, and fecal properties in elderly volunteers. Food Health and Nutrition Research (Journal of Nutritional Food) 2000:33-44

Abstract: DESIGN: Six elderly volunteers with the average age of 81.7 y were given 100 mL/d of fermented milk containing Bifidobacterium lactis FK 120 (BB-12), Lactobacillus acidophilus FK 205 (LA-5), Streptococcus thermophilus FK 303 (TH-3) and Streptococcus thermophilus FK 320 (ST-20) for 2 weeks in order to examine the effect of BB-12 on fecal flora and fecal properties. RESULTS: BB-12 was detected within the range of $10^6.6-8.9$ cfu/g in the feces of five of the six volunteers. Although a high incidence of B. adolescentis was detected before the intake, BB-12 was predominant during the intervention period. The ratio of Bifidobacteria to fecal bacteria was significantly increased (P<0.05), and the number of Clostridium perfringens and Clostridium-others was significantly decreased (P<0.05). Furthermore, an improvement of diarrhea with decreased fecal water, and a significant (P<0.05) decrease of fecal odor was observed. It should be noted that the authors only highlight BB-12.



Research field: Gastrointestinal Health

Research subfield: Inflammatory bowel disease / Irregular bowel movements / Microbiota

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: > 50 billion or < 5 million (heat-treated)

Product formulation: Fermented milk

Reference number: 0383

Laake, et al. Influence of fermented milk on clinical state, fecal bacterial counts and biochemical characteristics in patients with ileal- pouch- anal-anastomosis. Microb. Ecol. Health Dis. 1999;11:211-217

Abstract: Pouchitis is a condition with acute or chronic inflammation in the ileal pouch of colectomized patients. A disturbed microecology in the pouch has been suggested as a possible cause. The present study was an attempt to investigate if a fermented milk product containing live lactobacilli and bifidobacteria might influence on the intestinal microecology of IPAA-patients. Five hundred ml of a fermented milk product containing live lactobacilli (La-5) and bifidobacteriae (Bb-12) (Cultura, TM), was given in its regular form or heat-treated, in a randomized, double blinded fashion, to 16 patients operated on with ileal- pouch- analanastomosis (IPAA) for ulcerative colitis (UC). Symptoms recordings, stool cultures and determination of 6 different microflora associated characteristics (MACs); (short-chain fatty acids (SCFAs), urobilinogen, mucin degradation, coprostanol, fecal tryptic activity (FTA), and beta-aspartyl glycin) were performed at inclusion, after 1 and 2 weeks. In the group given regular Cultura, daily stool frequency was reduced from median 5.8 to 2.8. It was unchanged in the group given heat-treated Cultura. With regular Cultura the number of lactobacilli increased significantly during intervention, and remained elevated one week thereafter. The number of bifidobacteriae increased significantly during intervention, but was back to baseline one week thereafter. With heat-treated Cultura, no significant change was observed. Significant reduction in stool frequency was observed among the patients given regular Cultura. No change was observed among those given heat-treated Cultura. No major effects on six MACs were observed.



Research field: Gastrointestinal Health
Research subfield: Irregular bowel movements

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5 Dosage CFU/day: 400 - 450 billion LA-5 and 250 - 400 billion BB-12

Product formulation: Fermented milk

Reference number: 0056

Alm, et al. Effect of a new fermented milk product "CULTURA" on constipation in geriatric patients. Horizon Scientific Press 1993

Abstract: Abstract; DESIGN: 23 elderly geriatric patients with a history of chronic constipation consumed either unfermented or fermented milk. The study ran over 4 periods of 5 - 6 weeks. RESULTS: There was a significant improvement in frequency of bowel movement (P<0.05). No negative side effects were observed, and the product appears unlikely to cause electrolyte disturbances that can follow chronic use of laxatives. Supplementation with Lactobacilli and Bifidobacteria can improve natural bowel transit time and elimination rate, and can diminish the need for laxatives in the elderly and severely immobilized patients.



Research field: Women's Health
Research subfield: Yeast vaginitis
Study type: Human study
Probiotic strain: L. acidophilus LA-5
Dosage CFU/day: > 23 billion
Product formulation: Fermented milk

Reference number: 0151

Hilton, et al. Ingestion of Yogurt Containing Lactobacillus acidophilus as Prophylaxis for Candidal Vaginitis. Annals of Internal Medicine 1992;116:353-357

Abstract: Objective: To assess whether daily ingestion of yogurt containing Lactobacillus acidophilus prevents vulvovaginal candidal infections. • Design: Crossover trial for at least 1 year during which patients were examined for candidal infections and colonizations while receiving either a yogurt-free or a yogurtcontaining diet. Patients served as their own controls. • Setting: Ambulatory infectious disease center in a teaching hospital providing tertiary care. • Patients: Thirty-three women with recurrent candidal vaginitis were eligible after recruitment from community practices and clinics and through advertising. Twelve patients were eliminated for protocol violations. Of the remaining 21 patients, 8 who were assigned to the yogurt arm initially refused to enter the control phase 6 months later. Thus, 13 patients completed the protocol. Interventions: Women ate yogurt for 6 months of the study period. • Measurements: Colonization of lactobacilli and Candida in the vagina and rectum; candidal infections of the vagina. • Main Results: Thirtythree eligible patients were studied. A threefold decrease in infections was seen when patients consumed yogurt containing Lactobacillus acidophilus. The mean (\pm SD) number of infections per 6 months was 2.54 \pm 1.66 in the control arm and 0.38 ± 0.51 per 6 months in the yogurt arm (P = 0.001). Candidal colonization decreased from a mean of 3.23 ± 2.17 per 6 months in the control arm to 0.84 ± 0.90 per 6 months in the yogurt arm (P = 0.001). • Conclusion: Daily ingestion of 8 ounces of yogurt containing Lactobacillus acidophilus decreased both candidal colonization and infection.



Research field: Gastrointestinal Health
Research subfield: Diarrhea / Microbiota
Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 4 billion Product formulation: Capsules Reference number: 0092

Black, et al. Effect of lactic acid producing bacteria on the human intestinal microflora during ampicillin treatment. Scand.J.Infect.Dis. 1991;23:247-254

Abstract: 20 healthy volunteers participated in a double blind study concerning the effect of lactic acid producing bacteria on the intestinal microflora during ampicillin treatment. 10 volunteers received 500 mg ampicillin tablets t.i.d. together with capsules containing lactic acid producing bacteria (Lactobacillus acidophilus and Bifidobacterium bifidum) for 7 days, and the other 10 volunteers were given 500 mg ampicillin tablets together with placebo capsules t.i.d. for 7 days. Both groups of volunteers continued the intake of the capsules t.i.d. for another 14 days after the ampicillin administration had been completed. The number of enterococci, streptococci and corynebacteria decreased during ampicillin administration but returned to normal levels after 14 days. Yeasts increased during the antibiotic treatment but returned to the same levels as before treatment within 14 days. Escherichia coli strains were suppressed in most volunteers during ampicillin administration. The numbers of anaerobic gram-positive cocci and rods decreased in most subjects during ampicillin treatment but were normalized within 2 weeks. Bacteroides strains were recovered in higher numbers in the lactic acid producing bacteria group compared to the placebo group. The volunteers receiving lactic acid producing bacteria were recolonized slightly faster than those having placebo. There were adverse effects observed in 3 subjects receiving ampicillin plus placebo. In the lactic acid producing bacteria group, one subject had diarrhoea on day 3 to on day 3 to day 7.



Research field: Gastrointestinal Health
Research subfield: Lactose intolerance
Study type: Human study
Probiotic strain: Lacidophilus LA-5
Dosage CFU/day: 4 - 40 billion

Product formulation: Other **Reference number:** 0115

Lin, et al. Influence of nonfermented dairy products containing bacterial starter cultures on lactose maldigestion in humans. J.Dairy Sci. 1991;74:87-95

Abstract: The effect of nonfermented dairy products containing yogurt or acidophilus cultures on lactose utilization by lactose-maldigesting humans was investigated. Yogurt and acidophilus milk containing 10(7) or 10(8) of Streptococcus thermophilus and Lactobacillus bulgaricus, or Lactobacillus acidophilus, respectively, were prepared using commercially processed 2% low fat milk. Immediately following inoculation, products were refrigerated. Lactose maldigestion was monitored by measuring breath hydrogen excretion at hourly intervals for 8 h following consumption of 400 ml of each test meal containing approximately 20 g of lactose. The yogurt milk containing 10(8) cfu/ml was shown to contain significant concentrations of microbial betagalactosidase (EC 3.2.1.23; approximately 3 U/ml), which remained stable for at least 14 d at refrigerator temperatures. Breath hydrogen peaks were delayed and significantly lower (approximately 20 ppm at 5 to 7 h) than control values (approximately 70 ppm at 4 h), and intolerance symptoms were eliminated in all subjects. Yogurt milk containing 10(7) cfu/ml demonstrated intermediate breath hydrogen values and was marginally significantly different from control values. Lactobacillus acidophilus strains with varying resistance to bile and total beta-galactosidase-producing potential were also tested. Only one strain, LA-1, which demonstrated low bile resistance and intermediate beta-galactosidase activity, was capable of significantly decreasing breath hydrogen values when 10(8) cfu/ml of milk was consumed.



Research field: Gastrointestinal Health

Research subfield: Diarrhea / Irregular bowel movements

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 12 billion Product formulation: Capsules Reference number: 0250

Sagen. Treatment of functional disturbance in the intestine by administration of lactic acid bacteria. Internal report. Internal report 1989:.

Abstract: DESIGN: 24 partly or completely immobile, nursing home patients with various intestinal function problems were included in a double blind trial. Patients received placebo or probiotic capsules for 4 weeks. Observations were made by the nursing staff. RESULTS: Intestinal function was improved in 56% of the group receiving probiotic compared to 10% of the placebo group (P=0.019). Improvements included effect on running diarrhea and severe constipation.



Research field: Gastrointestinal Health
Research subfield: Recovery / Microbiota

Study type: Human study

Probiotic strain: B. animalis subsp. lactis BB-12 and L. acidophilus LA-5

Dosage CFU/day: 12 billion Product formulation: Capsules Reference number: 0308

Black, Laulund. A study on the recovery of ingested, encapsulated Lactobacillus acidophilus and Bifidobacteria bifidum from doudenal fluid and faeces. Internal report 1988:.

Abstract: DESIGN: 4 healthy adults consumed 1 encapsulated (with an acid-resistant matrix) probiotic capsule at each meal for 1 week. Fecal samples were collected before, during and after the week ingesting capsules. Duodenal samples were taken before and periodically after ingestion. RESULTS: Both strains were found to be in the duodenum after ingestion (identification directly on agar), indicating survival through the stomach. BB-12 appears to have a greater ability than LA-5 to persist in the upper small intestine in vivo. The number of Bifidobacteria in the feces increased significantly during treatment (P<0.01), indicating adherence and colonization.