LACTOBACILLUS CASEI DN-114 001 STRAIN IN THE PREVENTION OF POSTOPERATIVE RECURRENCE OF CROHN'S DISEASE: A RANDOMISED, DOUBLE-BLIND PLACEBO-CONTROLLED TRIAL

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INTRODUCTION: Recurrence after intestinal resection for Crohn's disease (CD) is frequent and poorly controlled by classic therapy. Luminal bacteria may be involved in the occurrence of new lesions and particularly the adherent and invasive E. coli LF82 found in the ileum of 35% of these patients. Since manipulation of luminal flora with probiotics may influence local immunity, we investigated the efficacy of the Lactobacillus casei (L. casei) DN-114 001 in the prevention of CD recurrence.

AIMS & METHODS: In this European trial, 111 patients were randomised to receive during one year L. casei (6X10 E10 cfu/day) (n=53) or placebo started 21 days after curative ileocolonic resection. The primary endpoint was the rate of endoscopic recurrence at 1 year with a grade 2 of Rutgeerts' score.

RESULTS: At 1 year, endoscopic recurrence was observed in 28/39 (72%) in the L. casei group and 28/46 (61%) in the placebo group (p=0.27) without difference of severity. The rate of endoscopic recurrence was similar at 3 months (50% vs 43%). Clinical recurrence (CDAI>150) was observed at one year in 26% in the L. casei vs 29% in the placebo group (ns). Tolerability was good with a similar frequency of adverse events in the two group. Significantly less gastrointestinal AEs were reported in the L. casei group 38% vs. 66% in the placebo (p=0.033). E. coli LF82 frequency were similar in L. casei group (34%) or the placebo (33%) and was not associated with an enhanced risk of relapses. A significant decrease expression of chemokines mRNA was observed CCR9(p=0.01), CCR10 (p=0.05), MIP-2 (p=0.005) and MCP-1 alpha (p=0.006)in the ileal mucosa in L. casei group vs placebo.

CONCLUSION: L. casei DN-114 001 administered during 1 year in patients with CD was well tolerated but didn't prevent endoscopic and clinical recurrences after surgery.