Department of Food and Nutritional Sciences

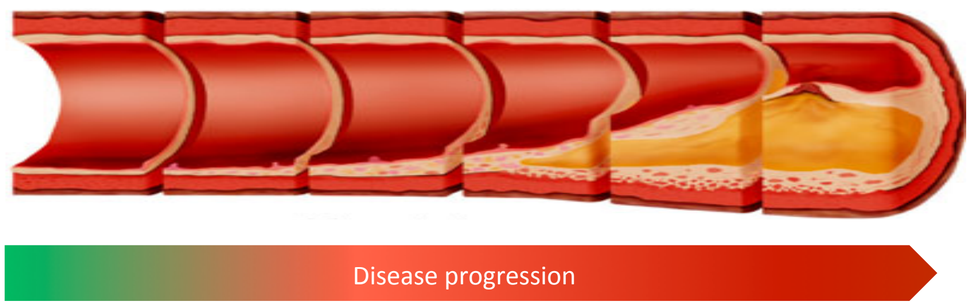
University of Reading

An assessment of the cholesterol-lowering efficacy of *Lactobacillus plantarum* LP-LDL® in adults with normal to mildly elevated cholesterol

Costabile A | Buttarazzi I | Kolida S | Quercia S | Baldini J | Swann JR | O'Hara S | Gibson GR

Introduction and Aims

Elevated blood cholesterol is an established risk factor for coronary heart disease. Total plasma cholesterol reduction in populations suffering from primary hypercholesterolemia may lower coronary heart disease incidence.



Progression of atherosclerosis due to LDL-cholesterol build up on arterial walls

The aim of this study was to investigate the cholesterol reducing capacity of Lactobacillus plantarum LP-LDL®, a strain selected for its high bile salt hydrolase activity and in vitro cholesterol reduction ability, in 49 normal to mildly hypercholesterolemic adults.

Primary study outcomes

- Effect on blood lipids (TC, LDL-C, HDL-C, TAG)
- Product safety (inflammatory biomarkers, occurrence of gastrointestinal side effects)

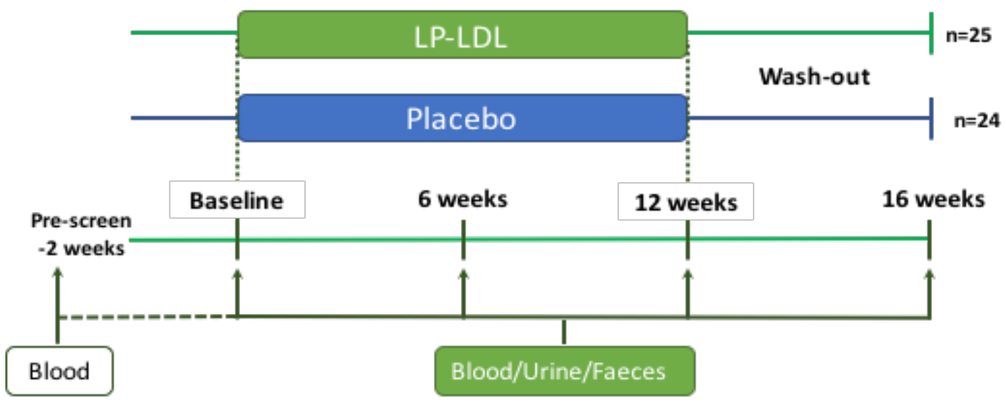
Secondary study outcomes

- Effect on blood pressure
- Effect on immune biomarkers (IL-6, IL-10 and TNF-α)
- Gut microbiome changes

Methods

Intervention

Single-centre, prospective, randomised, placebo-controlled, parallel-group human intervention study. Participants ingested twice daily encapsulated LP-LDL® (2x10^{9}CFU) or placebo before breakfast and dinner for 12 weeks.



Study group stratification

Active and placebo group participants were stratified according to baseline TC levels:

- Low baseline: TC < 5mM
- Mildly elevated baseline: TC 5-5.9mM
- High baseline: TC ≥ 6.0mM

Results

Product safety

No gastrointestinal side effects reported and no significant differences in stool morphology or frequency were observed. No findings of clinical significance were identified in the immune and inflammatory biomarkers. No differences were observed in serum or urinary metabolites comparing active vs. placebo.

Lipid profile & Cholesterol

Compared to placebo, TC (baseline to 12) weeks was reduced in all active groups. In the ≥ 6.0 mM group, TC significantly reduced by 36.7% (P=0.045) between baseline and 6 weeks.

LDL-C was reduced between baseline and 12 weeks in all the active treatment groups and not in the placebo group. LDL-C reduction was on average 7.2%, reaching 13.9% (P=0.03) in the TC < 5.0 mM group. HDL-C increased in the all-subject group by an average of 6.5%.

Blood pressure

There was group difference in blood pressure between baseline and 12 weeks, peaking in the 6-12 week time period whereby a significant reduction (P=0.003) in systolic blood pressure of 6mmHg (5.1%) in the active group vs. placebo.

Conclusions

This study confirmed the safety of *L. plantarum* LP-LDL® and demonstrated that it can positively impact on lipid profiles and blood pressure, both very significant cardiovascular risk factors. Our results, in an unoptimised product and in healthy adults, suggest efficacy similar or greater to 1.5-2.4g/day plant sterols/stanols.

Study highlights

An encapsulated daily dose of 4x10^{9}cfu *Lactobacillus plantarum* LP-LDL® :

- Was completely safe and well tolerated
- Lowered total cholesterol by up to 36.7%
- Lowered LDL cholesterol by up to 13.9%
- Increased HDL cholesterol by up to 6.5%
- Lowered systolic blood pressure by 5.1%

About Lactobacillus plantarum LP-LDL®

LP-LDL® was selected with OptiBiotix's OptiScreen® platform from a collection of 4,000 bacterial strains for its outstanding capacity to hydrolyse bile salts. This activity is potentially applicable to manage a range of health conditions such as high cholesterol, high blood pressure, glucose and energy regulation and vitamin metabolism.

Contact information

OptiBiotix Health plc | Science and Technology Centre, Whiteknights Campus, Reading (UK) | Email: spohara@optibiotix.com | +44(0) 7887 874392 | www.optibiotix.com