ISRCTN18123188 https://doi.org/10.1186/ISRCTN18123188

Safety and tolerability of the synbiotic product in elderly persons

Submission date	Recruitment status	[ ] Prospectively registered
05/05/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/07/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/02/2022	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Clostridium difficile (Cd) infection (CDI) is one of the most common health-care associated infections in hospitals and nursing homes. Symptoms include watery diarrhea, fevers, nausea and abdominal pain. There are different ways to prevent CDI. It has been found that hospitalised patients with Cd have lower levels of certain kinds of bacteria in the intestines (bowels). Research has shown that using a combination of xylitol (a sugar sweetener) with a specific kind of probiotic (live bacteria and yeasts) caleld L. plantarum INDUCIA® prevents the cells of Cd to be able to provide toxins and grow in the gut. The aim of this study is to test the safety and tolerability of a product containing L. plantarum INDUCIA® and xylitol in relatively healthy elderly persons.

Who can participate?
Adults over the age of 64 who have a stable diet and physical activity level.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group eat one package of product daily for three weeks that contains a lower dose of L. plantarum INDUCIA® and xylitol. Those in the second group eat one package of product daily for three weeks that contains a higher dose of L. plantarum INDUCIA® and xylitol. Participants are followed up for one week after the treatment to have samples of blood and stool taken to see if they experienced any issues.

What are the possible benefits and risks of participating?
Participants may benefit from the providing more information about their health condition and from a consultation with a doctor. There are no notable risks with participating however participants may experience discomfort when providing blood samples.

Where is the study run from?
BioCC OÜ (Estonia)

When is the study starting and how long is it expected to run for?
February 2016 to June 2018

Who is funding the study?
BioCC OÜ (Estonia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SYN-ELD2017

Study information

Scientific Title
Safety and tolerance testing of the synbiotic product of L. plantarum INDUCIA® and xylitol in elderly persons

Acronym
SYN-ELD

Study objectives
Synbiotic product of Lactobacillus plantarum INDUCIA® and prebiotic xylitol is well tolerated and causing no serious gastrointestinal complaints (adverse events) in relatively healthy elderly participants.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the University of Tartu, 20/03/2017, ref: 268/T-13

Study design
Randomised double-blind parallel dose intervention study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Relatively healthy elderly persons (over 64 years)

Interventions
Participants are randomly allocated to one of two groups. Randomisation is prepared by study statistician using statistical analysis software SAS 9.2 and participants are randomly allocated to one of the treatment groups applying a 1:1 allocation ratio.

Group 1 (Lower dose): Participants take one package of product daily for three weeks. The package contains a daily dose of product containing 5x10e9 cfu of L. plantarum INDUCIA® and 15 grams of xylitol. The daily dose is packed in food-grade aluminium foil sachets. The content of a sachet containing the test product should be mixed with cool or ambient temperature water.

Group 2 (Higher dose): Participants take one package of product daily for three weeks. The package contains a daily dose of product containing 5x10e9 cfu of L. plantarum INDUCIA® and 20 grams of xylitol per package. The daily dose is packed in food-grade aluminium foil sachets. The content of a sachet containing the test product should be mixed with cool or ambient temperature water.

Participants take the product daily for three weeks and follow up is done one week after the end of the treatment. Participants receive a follow up phone call at the third day of the study. Participants are asked to provide stool samples between day 8 to 14 and ebtween day 28 to day 30. Participants are assessed for an adverse events and have stool and blood samples taken. Participants can call to study doctor if they have any questions or concerns regarding the study or their health condition during the study.

Intervention Type

Supplement

Primary outcome measure
Adverse events are measured using the patient diary (follow chart), self administered follow-up questionnaire filled once per week, patient interviews at baseline, day three and day 21.

Secondary outcome measures
1. Presence of L. plantarum INDUCIA is measured by molecular methods from stool samples collected at baseline, between day 8 to 14, day 21, and between day 28-30
2. Occurrence of Clostridium difficile is measured by RIDA®QUICK Clostridium difficile GDH test and molecular methods from stool samples collected at baseline and day 21
3. Lipidogram is measured using blood tests at baseline and day 21
4. Level of ox-LDL values are measured using blood tests (using ELISA) at baseline and day 21
5. Primary and secondary bile acids are measured from stool samples using High Pressure Liquid Chromatograph (HPLC) at baseline and day 21
6. Short chain fatty acids are measured from stool samples using High Pressure Liquid Chromatograph (HPLC) at baseline and day 21
7. Evidence METS I (ferritin, interleukin-6 (IL-6), insulin, leptin, Plasminogen Activator Inhibitor-1 (PAI-1), resistin, Tumour Necrosis Factor α (TNFα)) are measured from fasting blood plasma using Randox Evidence Investigator at baseline and day 21

Overall study start date
01/02/2016

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Written informed consent
2. Aged over 64 years
3. Willingness to maintain a stable diet and physical activity level
4. Normal laboratory values with exception detailed in protocol
5. Normal, high normal and grade 1 systolic / diastolic blood pressure (≤159/99 mm Hg)
6. Normal, high normal and mild hypercholesterolemia

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
70

Key exclusion criteria

1. Pregnancy and breastfeeding
2. (Food) allergy
3. Intolerance to the investigational product / its ingredients
4. Diabetes
5. Eating disorder
6. Active weight loss > 5 kg in prior 3 months
7. Extensive exercise (daily trainings of professional athletes)
8. Drug or alcohol abuse
9. Participation in other studies within the last 30 days / during the study
10. Any history of gastrointestinal diseases
11. Acute infection within the last 2 weeks prior to baseline
12. Use of any antimicrobial agents within the preceding 1 month
13. Donor within the last 1,5 months prior to start of the study (i.e. baseline visit)
14. Use of any pre-, probiotic or food supplement within the last 2 weeks prior to start of the study
15. Chronic inflammatory diseases

Date of first enrolment
08/05/2017

Date of final enrolment
08/05/2018

Locations

Countries of recruitment
Estonia

Study participating centre
Bio-Competence Centre (BioCC)
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Sponsor information

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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Research organisation

Funder Name
Bio-Competence Centre of Healthy Dairy Products LLC Project EU48686

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/08/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Merle Rätsep merle.ratsep@tptak.ee

IPD sharing plan summary
Available on request