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Is a mixture of prebiotics and probiotics effective on gut microorganisms and the immune system in the elderly?

Submission date
31/01/2020

Recruitment status
No longer recruiting

Registration date
07/02/2020

Overall study status
Completed

Last Edited
28/03/2023

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Elderly people often have a chronic state of low-level inflammation leading to lower immunity. One of these consequences is a weaker intestinal barrier, which reduces the function of the digestive system and can cause constipation. The microorganisms in the gut can change in the elderly. Indeed, it has been shown that different species inhabit the elderly gut compared to the one of a young adult. The use of probiotics (live bacteria that can help in the establishment of a healthy gut microorganisms) and prebiotics (food ingredients that allow changes in the composition of the gut microorganisms because of the selective digestion of products by bacteria) has been shown to have beneficial effects on the health of elderly with some diseases like irritable bowel syndrome and inflammatory bowel disease.

The aim of this study is to compare prebiotics alone, a mixture of prebiotics and probiotics, and placebo in their effectiveness at treating common diseases in an elderly population

Who can participate?
Healthy volunteers aged from 60 to 80 years

What does the study involve?
Participants will take one stick of either prebiotic alone, a mixture of prebiotic and probiotic called DefensePlus, or an inactive product every day for 28 days, in a glass of water, away from meals. At enrolment, at the end of the 28 days of taking the supplement and follow-up 28 days after the supplement has been completed, participants will be required to give a saliva sample and a fecal sample and answer questionnaires.

What are the possible benefits and risks of participating?
Participants who take the symbiotic or the prebiotic mixtures could benefit from an improvement of CID symptoms. There are no notable risks involved in taking part in this study.

Where is the study run from?
Complife Italia Srl (Italy)

When is the study starting and how long is it expected to run for?
October 2018 to May 2019

Who is funding the study?
Regione Lombardia (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Clinical study to investigate the efficacy of formulations containing prebiotics and probiotics on the intestinal microbiota and on the immune system of elderly subjects

Study objectives
A symbiotic and a prebiotic formulation is clinically effective in terms of microbiota modulation and immune systems activation compared to a placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2019, the Independent Ethical Committee for Non-Pharmacological Clinical Study Trials (Via XX Septembre 30/4, Genova, Italy, 16121; a.scudieri@studinonfarmacologici.it; +39 01942790997), ref: 2018/14

Study design
A multicentre randomized double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Healthy elderly subjects, immunosenescence

Interventions
75 elderly subjects were enrolled and randomly allocated evenly in three groups using a computer-generated restricted randomization list. At enrolment, they received 28 days of the supplement and completed baseline evaluations.

Group 1 participants took a stick containing the prebiotic mixture (FOS (fructooligosaccharides from sucrose), inulin (from chicory), folic acid, vitamin B12, vitamin B6, sorbitol, sucralose, aroma, silicon dioxide, maltodextrin (from corn)).
Group 2 participants took a stick containing the symbiotic mixture DefensePlus (Lactobacillus acidophilus, Lactobacillus plantarum,Bifidobacterium animalis spp. Lactis, FOS (fructooligosaccharides from sucrose), inulin (from chicory), folic acid, vitamin B12, vitamin B6, sorbitol, sucralose, aroma, silicon dioxide, maltodextrin (from corn)).
Group 3 participants took a stick containing a placebo (folic acid, vitamin B12, vitamin B6, sorbitol, sucralose, aroma, silicon dioxide, maltodextrin (from corn)).

All participants took 1 stick a day for 28 days, in a glass of water, away from meals.

All participants were asked to return to the study centers 28 days after the last intake of the supplement for follow-up evaluation.

Intervention Type
Supplement

Primary outcome measure
1. Combined immunodeficiency symptoms, measured using a questionnaire of related symptoms, on a 4 points score at baseline and 28 days
2. Fecal calprotectin levels, determined by ELISA assays on stool samples collected at baseline and 28 days
3. Fecal beta-defensin 2 levels, determined by ELISA assays on stool samples collected at baseline and 28 days
4. Salivary IgA levels, determined by ELISA assays on salivary samples collected at baseline and 28 days.
5. Total Antioxidant Capacity, determined by FRAP assays on salivary samples collected at baseline and 28 days
6. Gut microbiota composition, determined through fecal microbiological analyses using V3-V4 16S NGS sequencing on DNA from stool samples collected at baseline and 28 days
7. Gut colonization, determined through fecal microbiological analysis using species-specific qPCR on DNA from stool samples collected at baseline and 28 days

Secondary outcome measures
1. Maintenance of combined immunodeficiency symptoms one month after treatment, determined using the questionnaire of related symptoms, based on a 4 points score at baseline, 28 and 56 days
2. Maintenance of fecal calprotectin levels one month after treatment, determined by ELISA assays on stool samples collected at baseline, 28 and 56 days
3. Maintenance of fecal beta-defensin 2 levels one month after treatment, determined by ELISA assays on stool samples collected at baseline, 28 and 56 days
4. Maintenance of salivary IgA levels one month after treatment, determined by ELISA assays on salivary samples collected at baseline, 28 and 56 days
5. Maintenance of total antioxidant capacity one month after treatment, determined by FRAP assays on salivary samples collected at baseline, 28 and 56 days
6. Maintenance of gut microbiota composition one month after treatment, determined through fecal microbiological analyses using V3-V4 16S NGS sequencing on DNA from stool samples collected at baseline, 28 and 56 days

Overall study start date
02/10/2018

Completion date
13/05/2019

Eligibility

Key inclusion criteria
1. Aged from 60 to 80 years on the day of inclusion
2. Ability to comply with all the trial procedures
3. Received an influenza vaccine more than 12 months prior to enrolment
4. Body Mass Index (BMI) between 18.5 and 24.99

5. Willingness to not vary the daily diet, fluid intake, and exercise routine during the trial period
6. Willingness to follow the proposed alimentary supplement for the trial period
7. Willingness to use only the supplement being tested during the trial period
8. Willingness to not use products likely to interfere with the product to be tested
9. Informed consent is given

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
75

Key exclusion criteria
1. Contraindications to the influenza vaccine
2. Immune system modulation treatment received within 4 weeks of the trial period
3. Immunosuppressant therapy lasting more than 2 weeks or stopped less than 3 months prior to the trial period
4. Influenza vaccination within one year of the trial period
5. Current antibiotic treatment
6. Known history of a chronic medical condition such as congenital heart disease, liver or kidney disease, or immune deficiency
7. Treatment with probiotics within 6 months of the trial period
8. Severe concurrent disease
9. Drug abuse
10. Alcohol abuse
11. Use of fiber products within 6 weeks of the trial period
12. Normal dietary intake exceptionally high in plant-based, high-fiber foods (fruits, vegetables, beans, whole grains, fortified foods), including those following a strict vegetarian diet
13. Dietary intake of probiotics
14. Pre-existing hypersensitivity to components contained in the probiotic
15. Any condition that the principal investigator deems inappropriate for participation
16. Adult protected by the law (under guardianship, or hospitalized in a public or private institution, for a reason other than the research, or incarcerated).
17. Subjects who have been recently involved in any other similar study

Date of first enrolment
20/02/2019

Date of final enrolment
18/03/2019

Locations

Countries of recruitment

Italy

Study participating centre
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Funder(s)

Funder type
Government

Funder Name
Regione Lombardia

Alternative Name(s)
Lombardy Region, Region of Lombardy

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Results and Publications

Publication and dissemination plan
Data will be published in relevant international peer-reviewed journals.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/06/2022	28/03/2023	Yes	No