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A controlled clinical trial to determine the potential of a prebiotic to beneficially influence the gut bacteria and immune defences of hospitalised elderly patients

Submission date
27/11/2008

Registration date
11/12/2008

Last Edited
03/05/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A double blind, placebo controlled, randomised, single-centred, parallel group study to determine the potential of a prebiotic to beneficially influence the colonic microflora and immune status of hospitalised elderly patients

Study objectives
The metabolic activity of the gastrointestinal environment outstrips that of the liver. This is due to the presence of microorganisms and their continuous interaction with their environment (including other bacteria, gut epithelium, mucosal immune system, central nervous system and the endocrine system). Recent data suggests that intestinal microflora, after 2 years of age, remains relatively constant over time. However, it has been noted that elderly people harbour lower levels of bifidobacteria which may compromise gut health. These changes may be explained in part by the alterations occurring within the body with ageing, such as reduction of gastric, biliary and pancreatic secretions, increased intestinal mucosal permeability, impaired intestinal mobility and immunological changes. Research over the past two decades has provided evidence that administration of probiotics and/or prebiotics could be used to help optimise gut microflora composition, as well as enhance immune function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire Research Ethics Committee, September 2008, ref: 08/H0504/127

Study design
Interventional double-blind randomised stratified parallel-design trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Gut microflora composition and immune function

Interventions

Patients are randomised to one of two groups (prebiotic/placebo). Patient will be supplemented with the treatment (dosage 5.5 g per day in powder format that can be dissolved in water or juice) for the duration of their hospitalisation and another 7 days after their release from the hospital. On day 1 patient numbers will be assigned and stratified according to reason for hospitalisation. Randomisation table to be obtained from the internet. The total duration of follow up is 2 weeks.

Intervention Type
Supplement

Primary outcome measure
To determine the effect of B-GOS on the faecal microflora of hospitalised elderly individuals, using the combination of 5'CY3-labelled 16S-ribosomal RNA oligonucleotide probes and epifluorescent microscopy known as Fluorescent In Situ Hybridisation (FISH). The main groups to be enumerated by this method will be: bifidobacteria, lactobacilli, clostridia, eubacteria, bacteroides and E. coli.

Assessed at the beginning and end of hospitalisation.

Secondary outcome measures
1. To investigate the effect of B-GOS on immunity, as a result of the improvement of the microflora composition, using routine immunological tests as well as cytokine analyses and phagocytosis, analysed in blood samples at the beginning and end of hospitalisation
2. To conduct a daily assessment of stool frequency, stool consistency, bloating, flatulence and abdominal pain, assessed daily based on the hospital records (nurse and doctor visits)
3. To assess the effect of B-GOS on the duration of hospital stay in elderly patients, assessed daily based on the hospital records (nurse and doctor visits)
4. To assess the effect of B-GOS on the incidence and duration of gastrointestinal infections manifest thorough diarrhoea, assessed daily based on the hospital records (nurse and doctor visits)
5. To assess the tolerability and confirm the safety of B-GOS in elderly hospitalised patients, assessed daily based on the hospital records (nurse and doctor visits)

Overall study start date
19/01/2009

Completion date
30/07/2009

Eligibility

Key inclusion criteria
1. Inpatients aged 65 or older, either sex
2. Ability to communicate well with the investigator and to comply with the requirements of the entire study
3. Patient has given written informed consent to participate and is willing to participate in the entire study
4. Patient is admitted to the hospital for a minimum of one week

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
300 patients

Key exclusion criteria
1. Patients lacking capacity who are therefore unable to consent
2. Diarrhoea on admission, within the preceding week or reported recurrent diarrhoea
3. Severe allergy or any history of severe abnormal drug reaction, drug or alcohol abuse
4. Intake of more than two courses of antibiotics in the previous four weeks
5. Former participation in another study involving prebiotic or probiotic supplements or investigational drugs within the previous 1 month, or intention to use such drugs during the course of the study
6. Undergone surgical resection of any part of the bowel
7. Currently prescribed immunosuppressive drugs including oral steroids
8. Patients with any heart valve replacement or history of rheumatic heart disease or infective endocarditis
9. Severe life threatening illness

Date of first enrolment
19/01/2009

Date of final enrolment
30/07/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Reading
Reading
United Kingdom
RG6 6AP

Sponsor information

Organisation
Clasado Ltd (UK)

Sponsor details
c/o Dr George Tzortzis
5 Canon Harnett Court
Wolverton Mill
Milton Keynes
United Kingdom
MK12 5NF

Sponsor type
Industry

Website
http://www.clasado.com

ROR
https://ror.org/04e5xac72

Funder(s)

Funder type
Industry

Funder Name
Clasado Ltd (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration