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An evaluation of the efficacy of the pre-biotic BENEO Synergy1 (combination oligofructose and high polymer-inulin) in the treatment of antibiotic associated diarrhoea

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 07/12/2015	**Condition category** Digestive System	

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
N0227185807

Study information

Scientific Title
An evaluation of the efficacy of the pre-biotic BENEO Synergy1 (combination oligofructose and high polymer-inulin) in the treatment of antibiotic associated diarrhoea

Study objectives
To investigate whether the duration of antibiotic-associated diarrhoea and clostridium difficile infection can be reduced by the use of the pre-biotic BENEO synergy 1.

Secondary Research Objective:
Can the recurrence of Clostridium difficile diarrhoea be reduced by using the prebiotic BENEO synergy 1?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Diarrhoea

Interventions
This trial will be piloted in the three medical ward at the Friarage Hospital, Northallerton prior to extension to wards 3, 4 and 12 at James Cook University Hospital (SJUH). These three wards specialise in healthcare for the elderly and have proportionately high rates of C. difficile infection. Other clinical trials using fructans have shown that 12 grams a day provides an

effective though easily tolerated dose. The Friarage Hospital pharmacy has agreed to issue the Synergy 1 or Sucrose placebo according to computer randomisation. The pharmacy at SJUH will also be approached prior to extension there. The powders will be in numbered but otherwise identical containers; the pharmacy will keep the key.

Patients will be provided with a 28-day course of the synergy 1. As synergy 1 is a food supplement and not a drug it will not be necessary for patients primary clinician to prescribe the supplement. It is hoped that nurses will be able to administer the treatment. This is to be achieved with a supplementary prescribing form attached to the patient's drug card. Awareness of the trial will be disseminated as widely as possible particularly amongst nursing staff on the target wards, and approval will be requested from all relevant consultants prior to starting the trial. The infection control nurses at Friarage Hospital have also agreed to participate.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oligofructose, high polymer-inulin

Primary outcome measure
Time to discontinuation of diarrhoea defined as greater than 3 loose stools in 24 hours. As would be standard clinical practice, all patients must have a baseline stool sample to check for C. difficile infection.

Secondary outcome measures
Incidence of clinical recurrence of C. difficile infection during the period of follow up.

Overall study start date
01/10/2006

Completion date
30/01/2007

Eligibility

Key inclusion criteria
1. Patients isolated or barrier nursed as a result of diarrhoea
2. Have received antibiotics in the preceding week
3. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
134

Key exclusion criteria
1. Patients unable to give informed consent
2. Restricted oral intake
3. Those with diabetes

Date of first enrolment
01/10/2006

Date of final enrolment
30/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Tees Hospitals NHS Trust
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health
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Sponsor type

Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS Trust (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