

An evaluation of the efficacy of the pre-biotic BENE0 Synergy1 (combination oligofructose and high polymer-inulin) in the treatment of antibiotic associated diarrhoea

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/12/2015	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
N0227185807

Study information

Scientific Title

An evaluation of the efficacy of the pre-biotic BENE0 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 BENE0 synergy 1.

Secondary Research Objective:

Can the recurrence of Clostridium difficile diarrhoea be reduced by using the prebiotic BENE0 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

South Tees Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration