

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 07/12/2015	<b>Condition category</b> Digestive System	<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

### Contact name

Dr John Hancock

### Contact details

South Tees Hospitals NHS Trust  
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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 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

## 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