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Dietary oligofructose in the prevention of antibiotic associated diarrhoea in elderly patients

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 06/01/2009	**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
N0544103828

Study information

Scientific Title

Study objectives
The purpose of this study is to see if the incidence of antibiotic related diarrhoea in elderly patients can be reduced by increasing colonic bifidobacteria concentrations with the concomitant prescription of oligofructose. Patients for the study will be identified by asking the Medical and Department for the Elderly teams if they had admitted any suitable patients. A brief clinical and drug history would be taken.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Digestive System: Diarrhoea

Interventions
The volunteers would then be randomly allocated to one of two groups.

Group A will take a placebo (10 g/day of sucrose powder) or group B 10 g/day of oligofructose. The trial powders will be administered by the ward nursing staff along with the volunteers' normal medication. Volunteers will take the trial powders for the length of time they are taking antibiotics and for a further 7 days after stopping antibiotics. Volunteers will be assessed continuously by recording on a stool form using a four point scale (1 hard, 2 lumpy, 3 mushy and 4 loose) and interdefecatory intervals. Both give an indication of intestinal transit rate. Recordings will be done by the patient or nursing staff as appropriate. The volunteers will be followed up for 7 days after stopping the oligofructose or placebo. The volunteer will have further stool samples sent to be analysed for the presence of Clostridium difficile toxin if they

develop diarrhoea during the study. The study's end point is the occurrence of diarrhoea due to Clostridium difficile.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/06/2000

Completion date
15/06/2003

Eligibility

Key inclusion criteria
250 volunteers >65 years old.

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
250

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
16/06/2000

Date of final enrolment
15/06/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Box No 201A
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/02/2005		Yes	No