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What happens to the bacteria in the gut in patients who are receiving tube feeding with additional carbohydrate

Submission date	Recruitment status	[_] Prospectively registered
10/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/01/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/12/2013	Nutritional, Metabolic, Endocrine	

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
07/H0702/41

Study information

Scientific Title
Comparing the colonic microbiota, faecal short chain fatty acids and immune status among patients receiving enteral feeding: the effect of additional fructo-oligosaccharides

Acronym
ETF (Enteral Tube Feeding)

Study objectives
To investigate the effect of additional fructo-oligosaccharides (FOS) supplementation on the faecal microbiota, short-chain fatty acids (SCFA), faecal pH, immune status and faecal output in patients receiving enteral tube feeding (ETF) for two-weeks.

Please note that as of 03/10/2008 this record was updated to include an extension to the anticipated end date, and an increase to the target number of participants. The initial anticipated end date of this trial was 30/09/2008 and the initial target number of participants was 20.

As of 08/07/2009 this record was further updated to indicate that it is now multicentre, with one further centre in the UK, and the anticipated end date of this trial was thus extended from 30/06/2009 to 30/09/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Barking and Havering Local Research Ethics Committee gave approval on the 12th November 2007 (provisionally granted subject to minor amendments) (ref: 07/H0702/41). Full ethics approval granted on the 14th December 2007. Amendment approved 19th September 2008.

Study design
Multicentre randomised prospective double-blinded, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Enteral tube feeding and fructo-oligosaccharides supplementation

Interventions
Twenty patients from the ICU who will be starting ETF with the routine fibre formula will be recruited. Ten patients will be randomly assigned to receive an additional 7 g of FOS per day while the other ten patients will receive 7 g of an identically packaged carbohydrate /maltodextrose (placebo) for 14 days. Giving the patient the additional 7 g of FOS or maltodextrose will start following the collection of first stool sample after enrolment to the ETF study.

Randomisation will be conducted using the EPISTAT program. The principal investigator will be kept blinded to whether the patient is receiving the additional 7 g of FOS or the additional 7 g of maltodextrose. A copy of the blinding code will be kept by the lead research nurse on ICU in the unlikely event that they need to unblind the study.

The 7 g of FOS or the identically packaged inactive carbohydrate will be dissolved in 50 ml of sterile water and flushed via the feeding tube daily by the nurse in charge. Water flushes to ETF patients are part of routine clinical care in the intensive care unit. The principal investigator will assist the nurse in charge in ensuring patients receive the correct additional carbohydrate and this will be monitored daily.

Stool samples will be collected by the principal investigator using normal routine stool sample collection procedures. Three faecal samples will be taken from each patient at baseline following starting ETF but prior to additional FOS (day 0), during additional FOS (day 6 - 8) and at the end of additional FOS (day 12 - 14).

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fructo-oligosaccharides (FOS) supplementation

Primary outcome measure
Difference in the colonic microbiota (measured using fluorescent in-situ hybridisation).

Secondary outcome measures
1. Incidence of diarrhoea (measured using King's Stool Chart)
2. Faecal samples will be analysed for:
2.1. SCFA concentrations
2.2. pH
2.3. C. difficile enterotoxin A/B
2.4. Faecal secretory Immunoglobulin A (IgA)

Overall study start date
15/01/2008

Completion date

30/09/2009

Eligibility

Key inclusion criteria
1. Intensive care unit (ICU) patients
2. Adult patients (both male and female)
3. Exclusive ETF with fibre formula

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 patients (as of 03/10/2008)

Key exclusion criteria
1. Patients receiving lactulose
2. Patients with gastrointestinal disease or gastrointestinal surgery
3. Patients currently receiving chemotherapy or gastrointestinal radiation therapy

Date of first enrolment
15/01/2008

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Room 4.46, Franklin- Wilkin's Building
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Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

Website
http://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King's College London (UK)

Funder Name
University of Malaya (Malaysia)

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

Malaysia

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	01/06/2011		Yes	No
Results article	results	01/12/2014		Yes	No