

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

Submission date
10/12/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
18/01/2008

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
03/12/2013

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

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

London

United Kingdom

SE1 9NH

Sponsor information

Organisation

King's College London (UK)

Sponsor details

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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 |