ISRCTN61157513 https://doi.org/10.1186/ISRCTN61157513

Modulation of gut function using Gut Specific Nutrients in the critically ill

Submission date 12/04/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/04/2009	**Overall study status** Completed	
Last Edited 24/03/2011	**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
LREC/04/378

Study information

Scientific Title
Modulation of gut function using gut specific nutrients in the critically ill: a double blind, placebo controlled, randomised clinical trial

Acronym
GSN study

Study objectives
The aim of this study is to determine whether or not the use of a cocktail of gut specific nutrients would enhance recovery of gut function and to assess if this is associated with other clinical benefits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scarborough Hospital Local Research Ethics Committee approved on the 1st March 2004 (ref: LREC/04/378)

Study design
Double-blind placebo-controlled randomised clinical 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
Gut failure

Interventions
Enrolled patients were randomised to either a control group (receiving placebo) or a study group (receiving a gut specific nutrient cocktail of glutamine, multivitamins and antioxidants [Forceval], probiotics [Trevis] and the prebiotic oligofructose).

Total duration of treatment/placebo = 1 month (30 days)
Follow-up for both treatment and placebo arms = 3 months

Intervention Type
Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Glutamine, multivitamins and antioxidants [Forceval], probiotics [Trevis], oligofructose

Primary outcome measure
Time to the return of normal gut function, measured hourly from recruitment to return of gut function.

Secondary outcome measures
1. Episodes of feed intolerance, measured daily for duration of stay
2. Numerous nutritional parameters
3. Use of opiates, total quantity measured for duration of stay, day 30 and day 90
4. Fluid balance, measured daily for duration of stay
5. The need for surgery, measured daily for duration of stay, on day 30 and day 90
6. Duration of intravenous infusions, measured daily for duration of stay
7. Serial intestinal permeability, measured on recruitment, on day 30 and day 90
8. Serial Acute Physiology and Chronic Health Evaluation II (APACHE II) scores, measured on recruitment, weekly during admission, on day 30 and day 90
9. Other single organ failures, measured daily for duration of stay, on day 30 and day 90
10. Occurrence of septic, non-septic, and feed-related complications, measured daily for duration of stay, as well as mortality (measured throughout the 90 day follow-up period) and length of ICU and hospital stay (measured on discharge from ICU/hospital)
11. Need for patient readmission, measured after discharge to day 90
12. Total number of general practitioner (GP) visits, measured after discharge to day 90
13. Anthropometric measurements, measured on recruitment, weekly during admission, on day 30 and day 90
14. Hospital anxiety and depression (HAD) scores, measured on recruitment and then on day 30 and day 90
15. Pain and fatigue scores, measured on recruitment, weekly during admission, on day 30 and day 90

Overall study start date
01/03/2004

Completion date
30/07/2006

Eligibility

Key inclusion criteria
Critically ill patients (aged greater than or equal to 18 years, either sex) with inadequate gut function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Failure to obtain consent (or assent by the next-of-kin)
2. Known intolerance to one or more of the study preparations
3. Aged less than 18 years
4. Pregnancy
5. Patients who are strictly 'nil-by-mouth' and therefore unable to receive the study preparations or appropriate placebos

Date of first enrolment
01/03/2004

Date of final enrolment
30/07/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of General Surgery
Scarborough
United Kingdom
YO12 6QL

Sponsor information

Organisation
Scarborough and North East Yorkshire Healthcare NHS Trust (UK)

Sponsor details
Scarborough General Hospital
Woodlands Drive
Scarborough

England
United Kingdom
YO12 6QL

Sponsor type
Hospital/treatment centre

Website
http://www.scarborough.nhs.uk/

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
Scarborough and North East Yorkshire Healthcare NHS Trust (UK)

Funder Name
The Combined Gastroenterology Research Fund (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	01/11/2010		Yes	No