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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre
Department of General Surgery

Scarborough United Kingdom YO12 6QL

Sponsor information

Organisation

Scarborough and North East Yorkshire Healthcare NHS Trust (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

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