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Refeeding risks in patients requiring nutrition support

Submission date 12/05/2010	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/05/2010	**Overall study status** Stopped	
Last Edited 09/06/2015	**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
2007-005547-17

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8212

Study information

Scientific Title
Refeeding risks in patients requiring nutrition support: a twin centre double-blind randomised controlled trial of parenteral nutrition support

Study objectives
We will conduct a randomised controlled trial to investigate the levels of nutrition support that minimise the dangers of refeeding syndrome in moderately/severely malnourished patients, while providing maximum nutrition for those in need. To do this we will conduct a twin-centre, prospective, randomised, controlled, double-blind trial of both physiological and biochemical markers of refeeding syndrome and clinical outcomes in patients needing intravenous nutrition support who, despite being at moderate or higher refeeding risk according to NICE defined criteria, are commenced at close to NICE recommended cautious levels, or more generous feeding levels (close to estimated requirements).

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=8212

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and Southwest Hampshire Research Ethics Committee, 28/07/2009, ref: 09/H0504/78

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact CTU@soton.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Gastrointestinal

Interventions

1. High rate parenteral nutrition: 48 hours of higher rates of feeding - 30 kcal/kg/day (including protein), 0.25 gN/kg/day
2. Low rate parenteral nutrition: 48 hours of lower rates of feeding - 15 kcal/kg/day (including protein), 0.125 gN/kg/day

Follow-up length: 1 months
Study entry: registration and one or more randomisations

Updated 09/06/2015: the trial was stopped in December 2013 due to recruitment issues.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Refeeding Syndrome, measured within 1 week of randomisation

Secondary outcome measures
1. Clinical evidence of fluid overload, measured at day 2 of trial
2. Infective complications, measured within 1 week of randomisation
3. Intracellular electrolyte disturbance, measured on day 3
4. Length of stay, measured on day of discharge
5. Supplemental electrolyte prescription, measured within 1 week of randomisation

Overall study start date
17/05/2010

Completion date
16/05/2012

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. All consenting patients (minimum 18 years old, either sex) who require intravenous nutrition as assessed by the Southampton University Hospitals NHS Trust and the Royal Berkshire NHS Foundation Trust Nutrition Support Teams
2. Patients who do not require specialised parenteral nutrition regimens to meet their clinical needs
3. Patients who are at moderate or high risk of refeeding syndrome as defined by:
3.1. Moderate risk (one of the following criteria):
3.1.1. Body mass index (BMI) less than 18.5 kg/m^2
3.1.2. Unintentional weight loss greater than 10% in 3 - 6 months
3.1.3. Very little or no food intake for greater than 5 days
3.2. High risk (one of the following criteria):
3.2.1. BMI less than 16 kg/m^2

3.2.2. Unintentional weight loss greater than 15%
3.2.3. Very little nutritional intake for greater than 10 days
Or
Two of the following lesser criteria:
3.2.4. BMI less than 18.5 kg/m^2
3.2.5. Weight loss greater than 10%
3.2.6. Very little nutritional intake for greater than 5 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 230; UK sample size: 230

Key exclusion criteria
1. Patients at very high risk of re-feeding syndrome (two or more of the NICE criteria: BMI less than 16 kg/m^2, recent weight loss greater than 15% body weight within 6 months, greater than 10 days with no nutritional intake) or patients with a BMI less than 14 kg/m^2)
2. Levels of K/Mg/PO4 below lower limit of normal (LLN) range from the SUHT chemical pathology laboratory prior to feeding
3. Patients with oral nutritional intake
4. Intensive care patients (who often receive variable levels of additional enteral tube feeding)
5. Patients weighing 80 kg or more giving them an estimated energy requirement above 2400 kcal/day (as we feel giving patients more than 2400 kcal/day poses too great a risk)
6. Patients with pre-existing diabetes mellitus
7. Patients unable to give informed consent to take part

Date of first enrolment
17/05/2010

Date of final enrolment
16/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton University Hospitals NHS Trust
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Tremona Road
Southampton
England
United Kingdom
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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?
HRA research summary			28/06/2023	No	No