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Optimal levels of parenteral nutrition (PN) in the catabolic patient

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/07/2016	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
N0231150767

Study information

Scientific Title
Optimal levels of parenteral nutrition (PN) in the catabolic patient

Study objectives
To determine whether intravenous provision of nutrition at levels lower than those currently recommended in guidelines from the British Association of Parenteral and Enteral Nutrition (BAPEN) decrease PN related complications and are beneficial to clinical outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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 use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Parenteral nutrition

Interventions
A double blind, randomised trial of parenteral nutrition (PN) support during the first five days of feeding at around the mid-range of current BAPEN recommendations (30 Kcal/kg non-protein energy + 0.25 gN/kg) VS. levels equating the minimum 'maintenance' feeding for a healthy resting individual (15 Kcal/kg non-protein energy + 0.125 gN/kg)

Intervention Type
Other

Primary outcome measure

1. Anthropometric changes
2. Haematological and biochemical disturbances
3. Clinical outcomes - infections, fluid balance and oedema, duration of PN, length of hospital stay, and mortality

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2004

Completion date
01/06/2005

Eligibility

Key inclusion criteria
All consenting adults requiring PN, who do not require specialised regimes to meet their clinical needs. Preliminary analysis of the data will be undertaken once 50 subjects are recruited to each arm.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/02/2004

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton General Hospital
Southampton
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Sponsor information

Organisation
Department of Health

Sponsor details
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Southampton University Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding (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