

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/07/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Southampton General Hospital

Southampton

United Kingdom

SO16 6YD

Sponsor information**Organisation**

Department of Health

Funder(s)**Funder type**

Government

Funder Name

Southampton University Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration