

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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/07/2016	<b>Condition category</b> 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

**Contact name**  
Dr Mike Stroud

**Contact details**  
Institute of Human Nutrition  
West Wing, Level C  
Southampton General Hospital  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD  
+44 (0)1703 796317  
M.A.Stroud@soton.ac.uk

## 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  
United Kingdom  
SO16 6YD

## Sponsor information

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## 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