# Randomised trial of glutamine and selenium supplemented parenteral nutrition (PN) for critically ill patients

Submission date Recruitment status Prospectively registered 23/02/2005 No longer recruiting [ ] Protocol Statistical analysis plan Registration date Overall study status 24/02/2005 Completed [X] Results [ ] Individual participant data Condition category Last Edited 16/05/2011 Other

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Peter John Dawson Andrews

#### Contact details

Anaesthetics, Intensive Care & Pain Medicine University of Edinburgh Western General Hospital Crewe Road Edinburgh United Kingdom EH4 2XU

# Additional identifiers

Protocol serial number N/A

# Study information

Scientific Title

#### **Acronym**

SIGNET Trial

#### **Study objectives**

This prospective, multicentre, pragmatic, placebo-controlled trial examines whether the inclusion of the amino acid glutamine or additional selenium, or the two together, improve the outcome of critically ill patients, when given as part of parenteral nutrition support. The main outcomes are infections, mortality, length of hospital and ICU stay. An economic evaluation is an integral component of this trial.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

2 x 2 factorial pragmatic multicentre double-blind randomised controlled trial

#### Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Critically ill patients in intensive care

#### **Interventions**

Allocation will be to one of four groups for 7 days:

- 1. Standard parenteral nutrition (PN) bag, 12.5 g nitrogen, 2000 kcal daily, no glutamine or selenium
- 2. PN bag, 12.5 g nitrogen (including 20.2 g glutamine), 2000 kcal daily
- 3. Standard PN bag, 12.5 g nitrogen, 2000 kcal daily, 500 mcg selenium daily
- 4. PN bag, 12.5 g nitrogen (including 20.2 g glutamine), 2000 kcal daily, 500 mcg selenium daily

#### **Intervention Type**

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

Nitrogen, glutamine, selenium

#### Primary outcome(s)

1. Infections - counted as participants with new infection(s) in the first 14 days (based on the expected duration of effect and the length of follow-up in previous trials), using published

methods (infections based on Centers for Disease Control criteria)

- 2. Mortality on ICU and overall at six months
- 3. Acute hospital and ICU length of stay

# Key secondary outcome(s))

Days of antibiotic use; adverse events (see below); duration of PN use; alive, ventilator-free days as recommended by Rubenfield (26); patient quality of life measured by SF36 and EQ5D; costs to NHS, patients and carers/families; incremental cost per day in ICU saved and/or per quality adjusted life year (QALY). Data on all expected and unexpected adverse events, their severity and likelihood of causality by trial TPN are collected following a standard protocol, developed for the pilot (see enclosed PDF file). Once the trial office is informed of a Suspected Serious Adverse Reaction (SUSAR), it is reported to the MHRA within 7 days (none occurred during the pilot). Details of any SUSARs and Serious Suspected Adverse Reactions (SSARs) will also be provided in an annual safety report to the MHRA.

### Completion date

30/04/2009

# Eligibility

#### Key inclusion criteria

Any patient on intensive care unit (ICU) requiring PN (and expected to have at least half of daily nutritional requirements given by that route) will be eligible for entry into the trial.

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

## Key exclusion criteria

- 1. As the study is based in adult ICUs, occasional patients aged under 16 years of age will be excluded.
- 2. We also exclude pregnant women; and people with severe hepatic failure, severe metabolic acidosis or severe renal insufficiency based on contraindications to glutamine in the product information sheet.

#### Date of first enrolment

01/01/2004

### Date of final enrolment

30/04/2009

# Locations

#### Countries of recruitment

**United Kingdom** 

Scotland

Study participating centre
Anaesthetics, Intensive Care & Pain Medicine
Edinburgh
United Kingdom
EH4 2XU

# Sponsor information

# Organisation

NHS Lothian - University Hospitals Division (UK)

#### **ROR**

https://ror.org/03q82t418

# Funder(s)

## Funder type

Government

#### Funder Name

Chief Scientist Office of the Scottish Executive Health Department

#### Funder Name

Fresenius Kabi

#### **Funder Name**

Oxford Nutrition

#### **Funder Name**

Medical Research Council (MRC) (UK) (G0401633)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

# **Funding Body Type**

Government organisation

# **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

# **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	17/03/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes