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

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

Plain English summary of protocol
Not provided at time of registration

Study website
https://www.charttrials.abdn.ac.uk/signet/index.php

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Available to downlaod for each of the recruiting sites in https://www.charttrials.abdn.ac.uk /signet/pis.php

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/01/2004

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

Age group
Adult

Sex
Both

Target number of participants
500

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
Scotland

United Kingdom

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

Sponsor information

Organisation
NHS Lothian - University Hospitals Division (UK)

Sponsor details
Research & Development Office
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4SA

Sponsor type
Hospital/treatment centre

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

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?
Results article	results	17/03/2011		Yes	No