

Selenium replacement and outcome in critically ill septic patients.

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/07/2009	Condition category Signs and Symptoms	☐ Individual participant data

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
N0207104826

Study information

Scientific Title

Study objectives

To measure outcome of selenium replacement in critically ill septic patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Single-centre prospective randomized double blind controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Signs and Symptoms: Sepsis

Interventions

1. High selenium
2. Standard selenium

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Selenium

Primary outcome(s)

Study of Selenium replacement and outcome in critically ill septic patients.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/10/2004

Eligibility

Key inclusion criteria

Critically ill patients within the intensive therapy unit.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age <18yrs
2. Pregnant and lactating women
3. Patients not expected to survive >72 hrs
4. Refusal to participate
5. Chronic renal failure patient who is dialysis dependent
6. Severe gastrointestinal bleeding due to alcoholic liver disease
7. Patients known to have acquired AIDS, Hep B or C
8. Granulocyte count less than 1000/mm³ due to a cause other than sepsis

Date of first enrolment

17/09/2001

Date of final enrolment

31/10/2004

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Anaesthesia

Liverpool

United Kingdom

L7 8XP

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Liverpool and Broadgreen University Hospitals Trust (UK), No External Funding, NHS R&D Support Funding

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	01/02/2007		Yes	No