ISRCTN20492006 https://doi.org/10.1186/ISRCTN20492006

Selenium replacement and outcome in critically ill septic patients.

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr SM Mostafa

Contact details
Department of Anaesthesia
12th floor
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Single-centre prospective randomized double blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
17/09/2001

Completion date
31/10/2004

Eligibility

Key inclusion criteria
Critically ill patients within the intensive therapy unit.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200, 100 in each group

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
England

United Kingdom

Study participating centre
Department of Anaesthesia
Liverpool
United Kingdom
L7 8XP

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
Hospital/treatment centre

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

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	01/02/2007		Yes	No