A randomised controlled trial investigating the effect of strict glycaemic control on the incident of nosocomial infection in critically ill patients

Submission date	Recruitment status No longer recruiting	Prospectively registered			
29/09/2006		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
29/09/2006	Completed	[X] Results			
Last Edited	Condition category	[] Individual participant data			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0236173812

Study information

Scientific Title

Study objectives

- 1. To investigate the association between strict glycaemic control and the subsequent development of nosocomial infection.
- 2. To determine the relationship between nosocomial pneumonia and the presence of glucose in endotracheal secretion.

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Infections and Infestations: Nosocomial infections

Interventions

All ventilated patients will be randomised to 2 groups:

Group 1 - the treatment group: a continuous infusion of insulin will be started once blood glucose levels exceed 6.1 mmol/l and adjusted accordingly to maintain blood sugar levels between 4.4 and 6.1 mmol/l

Group 2 - the control group: insulin will be adjusted to maintain blood glucose levels <= 10 mmol /l

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Nosocomial infection.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2002

Completion date

01/05/2005

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100 subjects and 100 controls, total 200

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2002

Date of final enrolment

01/05/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Anaesthetics Department London United Kingdom SW17 0QT

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, 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

St George's Healthcare NHS Trust (UK), 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	Peer reviewed?	Patient- facing?
Results article	results on nosocomial pneumonia and the presence of glucose in endotracheal secretion	01/09 /2005	Yes	No