An investigation into whether tight glucose control improves mortality in patients admitted to combined Intensive Therapy Unit/High Dependency Unit (ITU/HDU)

Submission date	Recruitment status	Prospectively registered
30/09/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Completed	Results
Last Edited	Condition category	Individual participant data
05/12/2014	Other	Record updated in last year

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

N0247130746

Study information

Scientific Title

An investigation into whether tight glucose control improves mortality in patients admitted to combined Intensive Therapy Unit/High Dependency Unit (ITU/HDU)

Study objectives

Does intensive glucose control improve outcome in a population of Intensive Therapy Unit/High Dependency Unit (ITU/HDU) patients?

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Not Applicable

Interventions

Group 1: Intensive insulin therapy - the blood glucose will be maintained between 4.4 and 6.1 mmol/L using intravenous insulin therapy

Group 2: Conventional insulin therapy - the blood glucose will be maintained between 10.0 and 11.1 mmol/L using intravenous insulin therapy

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Insulin

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

10/03/2003

Completion date

30/06/2005

Eligibility

Key inclusion criteria

ITU/HDU patients

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

10/03/2003

Date of final enrolment

30/06/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre The Great Western Hospital Swindon United Kingdom SN3 6BB

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Swindon and Marlborough NHS Trust (UK)

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 summaryNot provided at time of registration