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The role of intensive insulin therapy in critically ill medical and surgical patients

Submission date 03/07/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/07/2005	**Overall study status** Completed	
Last Edited 18/05/2018	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2002.11

Study information

Scientific Title
The role of intensive insulin therapy in critically ill medical and surgical patients

Acronym
Insulin in ICU patients

Study objectives
Tight blood glucose control reduces mortality in critically ill patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee, 12/03/2003

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
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Critically ill medical and surgical patients

Interventions
This is a randomised controlled trial. Patients will be randomly assigned to receive intensive insulin therapy (maintenance of blood glucose at a level between 4.4 - 6.1 mM/l or 80 - 110 mg /dl) or conventional treatment (infusion of insulin only if the blood glucose level exceeded 11.1 mM/l or 200 mg/dl) and maintenance of glucose at a level between 10 - 11.1 mM/l or 180 - 200 mg/dl) throughout their stay in ICU.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Insulin

Primary outcome measure
All cause mortality in the ICU

Secondary outcome measures
1. Hospital outcome
2. Cause of death
3. ICU and hospital LOS
4. Mechanical ventilation duration
5. The need for renal replacement therapy
6. Transfusion requirements
7. ICU acquired infections
8. Causes of death

Overall study start date
01/01/2004

Completion date
30/11/2005

Eligibility

Key inclusion criteria
1. Adults (greater than 18 years old) able to give consent (directly or via proxy)
2. Random admission blood glucose level greater than 6.1 mM/l (greater than 110 mg/dl)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
522

Key exclusion criteria
1. Type I diabetes
2. Patients admitted with diabetic ketoacidosis
3. Patients with terminal illness (survival judged by the treating physician less than four weeks)
4. Patients with do not resuscitate (DNR) orders

5. Pregnancy
6. Patients with expected intensive care unit (ICU) length of stay (LOS) of less than 24 hours
7. History of hypoglycaemia during the same hospitalisation
8. Seizure disorder (known active in the last 6 months)
9. Post-cardiac arrest patients
10. Readmission to ICU within the same hospitalisation
11. Brain death
12. Liver transplant
13. Enrolled in another competing study
14. Refused consent
15. No consent within 24 hours of meeting inclusion criteria
16. Other reasons

Date of first enrolment
01/01/2004

Date of final enrolment
30/11/2005

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Fahad National Guard Hospital
Riyadh
Saudi Arabia
11426

Sponsor information

Organisation
King Fahad National Guard Hospital (Saudi Arabia)

Sponsor details
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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/009djsq06

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
King Fahad National Guard Hospital (Saudi Arabia) - ICU Research Fund

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	01/12/2008		Yes	No
Results article	nested cohort study results	16/05/2018		Yes	No