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

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

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
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
All cause mortality in the ICU

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

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

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 nested cohort study results	01/12/2008		Yes	No

Results article	16/05/2018	Yes	No