

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

<b>Submission date</b> 03/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/05/2018	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**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?
<a href="#">Results article</a>	results	01/12/2008		Yes	No
<a href="#">Results article</a>	nested cohort study results	16/05/2018		Yes	No