

# 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

**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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

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

[Results article](#)

16/05/2018

Yes

No