

The impact of hypocaloric diet with intensive insulin therapy on mortality and morbidity in adult critically ill patients

Submission date

22/07/2007

Recruitment status

No longer recruiting

Registration date

31/07/2007

Overall study status

Completed

Last Edited

14/04/2011

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

RC-2005.30

Study information

Scientific Title

Study objectives

Hypocaloric diet with or without intensive insulin therapy is associated with better outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Ethical Committee of King Fahad National Guard Hospital (ref: RC- 2005.30)

Primary study design

Interventional

Study design

Randomized controlled trial with concealed randomization using sealed envelopes.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Intensive care, critically ill patients

Interventions

All patients admitted to ICU are screened for eligibility. Once patient is eligible for study, informed consent is obtained from the next of kin. The patient is then randomized to one of the following arms:

1. Eu-caloric diet (target 90-100% of caloric requirement estimated by Harris-Benedict equation) and conventional insulin (insulin administered when the blood glucose level exceeds 11.1 mmol / liter with the use of insulin infusion in order to keep the blood glucose between 10.0-11.1mmol / liter)
2. Eu-caloric diet and intensive insulin (insulin administered when the blood glucose level exceeded 6.1mmol / liter with the use of insulin infusion to keep blood glucose between 4.4-6.1 mmol / liter)
3. Hypo-caloric diet (target 60- 70% of caloric requirement estimated by Harris-Benedict equation) and conventional insulin
4. Hypo-caloric diet and intensive insulin

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

insulin

Primary outcome(s)

ICU, 28 day and Hospital mortality.

Key secondary outcome(s)

1. ICU length of stay
2. Duration of mechanical ventilation
3. Incidence of nosocomial infections

Completion date

01/05/2008

Eligibility

Key inclusion criteria

1. Patients receiving nasogastric tube feeding
2. Aged >18 years
3. Staying >48 hours in Intensive Care Unit (ICU)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Refused consent
2. Terminal illness
3. DNR (Do Not Resuscitate; no code, no escalation) in first 48 hours of admission
4. Enteral feeding cannot be started within 48 hours
5. Total Parenteral Nutrition (TPN)
6. Oral feeding
7. Liver transplant
8. Seizures within last 6 months
9. Expected to stay less than 48 hours
10. Age less than 17 years
11. Readmission
12. Brain dead within 48 hours
13. Pregnancy
14. Post cardiac arrest
15. Enrolled in another study
16. Hypoglycemic coma
17. Blood glucose less than 6.1mmol in first 48 hours
18. Type 1 diabetes

Date of first enrolment

27/02/2006

Date of final enrolment

01/05/2008

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

Intensive Care Department

Riyadh

Saudi Arabia

11426

Sponsor information

Organisation

King Abdulaziz City for Science and Technology (KACST) (Saudi Arabia)

ROR

<https://ror.org/05tdz6m39>

Funder(s)

Funder type

Government

Funder Name

King Abdulaziz City for Science and Technology (KACST) (Saudi Arabia)

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	01/03/2011		Yes	No