ISRCTN96294863 https://doi.org/10.1186/ISRCTN96294863

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
[X] Results
[ ] 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
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)

Study design
Randomized controlled trial with concealed randomization using sealed envelops.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
ICU, 28 day and Hospital mortality.

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

Overall study start date
27/02/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Refused consent
2. Terminal illness
3. DNR (Do Not Recussitate; no code, no escalation) in first 48 hours of admission
4. Enteral feeding cannot be started within 48 hours
5. Total Parentral 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)

Sponsor details
P.O. Box 6086
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Saudi Arabia
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+9661 4833444
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Sponsor type

Government

Website
http://www.ngha.med.sa/en/m-cities/cr/dep/icu/index.htm

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

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	01/03/2011		Yes	No