Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of insulin therapy on morbidity and mortality of critically ill patients admitted to intensive care unit

Protocol summary

Summary

Hyperglycemia is associated with increased mortality and morbidity. Current evidence has controversies about Intensive Insulin Therapy (IIT) and its effect on reducing mortality in critically ill patients. In this trial we evaluated the effect of IIT on mortality and morbidity of critically ill patients. Sixty adult patients admitted to surgical intensive care unit will be enrolled in this study. Patients with ICU length of stay less than 3 days, DNR (do not resuscitate) order and ability to take oral feeding will be excluded. Patients will be randomly allocated to intensive insulin therapy group (with a target blood sugar of 80-120 mg/dl) and control group (receive insulin if blood glucose is more than 200 mg/dl). Study will be continued through the ICU stay of all patients. Mortality and Morbidity(Acute Kidney Injury, Renal Replacement Therapy, Bactremia, Hypoglycemia and transfusion requirements) of patients in two groups will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011062582N1**
Registration date: **2010-12-08, 1389/09/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-08, 1389/09/17

Registrant information

Name

Ata Mahmoodpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-11-10, 1389/08/19

Expected recruitment end date

2011-11-10, 1390/08/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of insulin therapy on morbidity and mortality of critically ill patients admitted to intensive care unit

Public title

The effect of insulin therapy on outcome of critically ill patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: adult (more than 18 y.o) critically ill patients who admitted to surgical ICU (Intensive Care Unit). Exclusion criteria: Patients with Intensive Care Unit length of stay less than 3 days, patients who can tolerate oral feeding, patients with DNR (DO NOT RESSUSCITATE) order.

Age

From **18 years** old to **81 years** old

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Tabriz University
City
Tabriz
Postal code
Approval date
2009-05-20, 1388/02/30
Ethics committee reference number
88/1-4/3

Health conditions studied

1

Description of health condition studied
External causes of morbidity and mortality
ICD-10 code
R73.9
ICD-10 code description
Hyperglycaemia, unspecified

Primary outcomes

1

Description
mortality
Timepoint
Daily, during the ICU stay
Method of measurement
physical exam

Secondary outcomes

1

Description
morbidity (Acute Kidney Injury, Transfusion requirement, bactremia, hypoglycemia)
Timepoint
Daily, during the ICU stay
Method of measurement
Creatinine increasing for Acute Kidney Injury, Number of packed cell which is transfused for transfusion requirement, positive blood culture and systemic inflammatory response syndrome for bacteremia, blood glucose less than 60 mg/dl as hypoglycemia

Intervention groups

1

Description
Intervention group will recieve insulin drip based on following formula: (BS-120) / 20. For hypoglycemic events insulin drip will be hold and patients will receive Dextrose Water 50% based on the formula: (100-BS)x0.4. Blood Sugar is measured every hour and during hypoglycemia each 30 minutes.
Category
Treatment - Drugs

2

Description
In Control group: patients receive bolus doses of insulin only in blood glucose more than 200 mg/dl based on the following formula: (BS-180)/30. Blood glucose will be monitored three times daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
General ICU of Shohada hospital
Full name of responsible person
Ata Mahmoodpoor
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person

Alireza Ostad Rahimi

Street address

Faculty of Health and Nutrition

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Position

Assistant professor, PhD of nutrition

Other areas of specialty/work

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Position

Director of ICU/ Assistant professor/Fellowship of Critical Care Medicine

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty