

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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)

##### Phone

+98 914 116 0888

##### Email address

mahmoodpoora@tbzmed.ac.ir

##### 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 receive 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:  $(100-BS) \times 0.4$ . 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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ata Mahmoodpoor

**Position**

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

**Other areas of specialty/work**

**Street address**

General ICU, Shohada Hospital, El-Goli street

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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*