

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of glycemic control by insulin sliding scale protocol versus continuous insulin infusion on malondialdehyde (MDA) and protein carbonyl (PCO) in non-diabetic hyperglycemia patients in ICU

Protocol summary

Summary

The purpose of this study is to compare the effect of blood glucose (BG) control by Continuous Insulin Infusion (CII) and Insulin Sliding Scale (ISS) on malondialdehyde (MDA) and protein carbonyl as oxidative stress biomarkers in non-diabetic ICU patients. In this prospective, randomized clinical trial, 60 adult non-diabetic patients with stress induced hyperglycemia, defined as BG>180mg/dL, will be recruited from ICU of Imam Hossein Hospital, Tehran, Iran. Patients will be entered to CII and ISS groups, randomly. In CII group the insulin infusion rate will be determined by BG level based on institutional protocol. The target of BG is 140-180mg/dL in both groups and the duration of the study is 7 days. Beside clinical data, MDA and PCO levels will be determined at baseline, 3rd and 7th days of the study. Primary outcome measures are comparison of MDA and PCO and their changes in two group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050810178N6**

Registration date: **2014-06-01, 1393/03/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-01, 1393/03/11

Registrant information

Name

Mohammad Sistanizad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of glycemic control by insulin sliding scale protocol versus continuous insulin infusion on malondialdehyde (MDA) and protein carbonyl (PCO) in non-diabetic hyperglycemia patients in ICU

Public title

Blood glucose control in ICU: insulin sliding scale versus continuous insulin infusion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Blood glucose more than 180 mg/dL in ICU 2) No diabetes history 3) At least 18 years old
Exclusion criteria: 1) Less than 18 years old 2) Diabetes diagnosis during the study 3) Lack of patient or patient's relatives Consent 4) Transport to other units or death within 8 days of entrance

Age
From **18 years** old to **139 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
SBMU Medical Ethics and Law Research Center

Street address
Velenjak Street, Shahid Chamran High Way

City
Tehran

Postal code

Approval date
2012-09-16, 1391/06/26

Ethics committee reference number
8283/400

Health conditions studied

1

Description of health condition studied
stress hyperglycemia

ICD-10 code
R73.9

ICD-10 code description
Hyperglycaemia, unspecified

Primary outcomes

1

Description
Malondialdehyde (MDA)

Timepoint

Baseline, 3rd and 7th days of study

Method of measurement
Biochemistry

2

Description
Protein Carbonyl (PCO)

Timepoint
Baseline, 3rd and 7th days of study

Method of measurement
Biochemistry

Secondary outcomes

1

Description
Sequential Organ Failure Assessment (SOFA)

Timepoint
Daily

Method of measurement
Scoring system (consists of 6 scoring criteria)

2

Description
ICU stay

Timepoint
Daily

Method of measurement
Days

3

Description
Daily insulin requirement

Timepoint
Daily

Method of measurement
Insulin unit

4

Description
Blood glucose

Timepoint
Daily average

Method of measurement
Every hour to every six hour, mg/dL

Intervention groups

1

Description
Control group: BG control by Insulin Sliding Scale
Intervention group: BG control by Continuous Insulin Infusion

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

ICU, Imam Hossein Hospital

Full name of responsible person

Mohammad Sistanizad, Pharm. D., Clinical Pharmacy
Specialist, Assistant Professor

Street address

Shaheed Madani St., Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh Shams

Street address

Velenjak St., Shahid Chamran Highway

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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

Faculty of Pharmacy, Shahid Beheshti University of
Medical Sciences

Full name of responsible person

Mohammad Sistanizad

Position

Assistant Professor / Clinical Pharmacy Specialist

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Position

Pharmacy doctorate / researcher

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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