

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of intensive versus conventional glycaemic control in patients on parenteral nutrition in intensive care unit.

Protocol summary

Summary

The purpose of this study is the Comparison of intensive versus conventional glycaemic control in patients on parenteral nutrition (PN) in intensive care unit. In this study, 32 patients 18 years old or older, were participated. Patients had head trauma, GCS 4-9, and received at least half of their needs through PN. Patients with Liver, kidney, heart, pancrease failure and/or diabetes were excluded from the study. Patients were randomly received intensive insulin therapy (continuous infusion) or conventional blood glucose control (12 hours checking). One of the most important results of tight glucose control is severe hypoglycemia that can lead to mortality. In this study, we want to compare intensive with conventional method with a minimal change in infusion chart.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111158108N1**

Registration date: **2011-12-08, 1390/09/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-08, 1390/09/17

Registrant information

Name

Neda Mousavi

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

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+98 51 1800 2103

Email address

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2011-02-04, 1389/11/15

Expected recruitment end date

2011-07-01, 1390/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intensive versus conventional glycaemic control in patients on parenteral nutrition in intensive care unit.

Public title

Comparison of intensive versus conventional glycaemic control in patients on parenteral nutrition

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 18 years or older with GCS 4-9 with muscle erosion, diarrhea or high residue that couldn't feed through oral or enteral rout, were eligible for enrolling into the study. Patients on parenteral nutrition criteria received at least 50% of their calorie from parenteral nutrition. Exclusion criteria: Patients with liver; kidney; heart; pancrease failure and or diabetes

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 32

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad medical university

Street address

Biochemistry & Nutrition department, faculty of medicine, Mashhad medical university, Khorasan.

City

Mashhad

Postal code

Approval date

2011-01-03, 1389/10/13

Ethics committee reference number

thesis register+ethics:89341

Health conditions studied

1

Description of health condition studied

Hyperglycemia resulted from parenteral nutrition

ICD-10 code

R73.9

ICD-10 code description

Hyperglycaemia, unspecified

Primary outcomes

1

Description

Hyperglycemia

Timepoint

Every 2 hours in tight control group- every 12 hours in conventional group.

Method of measurement

Glucometer Kit.

Secondary outcomes

1

Description

During of hospital and ICU stay, mortality

Timepoint

14 & 28 days after intervention

Method of measurement

Observe & phone number

Intervention groups

1

Description

Intensive control: 50 unit regular insulin in 50 cc saline, continuous insulin infusion, blood glucose control every 2 hours and insulin infusion according to chart, administration of this method in 14 days.

Category

Treatment - Drugs

2

Description

Conventional control: blood glucose checking every 12 hours, regular insulin injection according to chart, administration of this method in 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Kamyab hospital in Mashhad

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad medical sciences university

Full name of responsible person

Marjan.Ardakanian

Street address

Room number:307, Ghoreishi department, Daneshgah street, Mashhad.

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Mashhad medical sciences university

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**

Mashhad medical sciences university

Full name of responsible person

Seyede Neda Mousavi

Position

Student

Other areas of specialty/work**Street address**

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Full name of responsible person

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Position

Assistant Professor

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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