Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Summary

The purpose of this study is the Comparison of intensive versus conventional glycemic control in patients on parentral 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

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Name of organization / entity
Mashhad University of Medical Science
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Iran (Islamic Republic of)
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+98 51 1800 2103
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kamgarm881@mums.ac.ir

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 parentral nutrition in intensive care unit.

Public title

Comparison of intensive versus conventional glycaemic control in patients on parentral 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 parentral 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, continious 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
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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