Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of perioperative strict blood glucose control before, during and after spinal surgery (posterior approach)in elective diabetic or glucose intolerance patients on the decrease of surgical site infection

Protocol summary

Study aim

Study of the effect of perioperative strict blood glucose control before, during and after spinal surgery (posterior approach)in elective diabetic or glucose intolerance patients on the decrease of surgical site infection

Design

This study is a one-blinded clinical trial. The study population will be included all patients with diabetes undergoing posterior approach spinal surgery referred to Imam Reza hospital of Kermanshah city. A total of 290 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

This study, which will be conducted at Imam Reza hospital of Kermanshah city is one-blinded one so that, participants are unaware of which intervention group they will be in and when will the blood glucose be controlled?

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetes or impaired glucose tolerance; Lack of any malignancy Exclusion criteria: Lack of follow-up; Migration

Intervention groups

In the first group, the blood glucose levels of patients undergoing spinal surgery during the beginning of anesthesia and during anesthesia are controlled by an anesthetist. In the second intervention group, patients who are ready for spinal surgery from two days before surgery, during anesthesia and one day after surgery, will be under strict control of blood glucose with insulin protocol to maintain it in the range of 100 to 140 0 mg/dec.

Main outcome variables

Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N102**
Registration date: **2018-09-25, 1397/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-25, 1397/07/03**
Update count: **0**

Registration date

2018-09-25, 1397/07/03

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-11, 1397/06/20

Expected recruitment end date

2018-11-11, 1397/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the effect of perioperative strict blood glucose control before, during and after spinal surgery (posterior approach)in elective diabetic or glucose intolerance patients on the decrease of surgical site infection

Public title
Study of the effect of strict blood glucose control before, during and after spinal surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diabetes or impaired glucose tolerance Lack of any malignancy Lack of malnutrition
Exclusion criteria:
Patients with debilitating or degenerative diseases Lack of follow-up Migration

Age
To **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **290**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly Individually by random number table via code receipt

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants have been blinded to which intervention group they are in

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
City
Kermanshah
Province
Kermanshah
Postal code
6715847141

Approval date
2018-05-22, 1397/03/01

Ethics committee reference number
ir.kums.rec.1397.154

Health conditions studied

1

Description of health condition studied
lumbar traumatic fracture

ICD-10 code
S32.0

ICD-10 code description
Fracture of lumbar vertebra

Primary outcomes

1

Description
Infection

Timepoint
For one month after spinal surgery

Method of measurement
On the basis of examination, radiography and blood tilth

Secondary outcomes

empty

Intervention groups

1

Description
In the first group, the blood glucose levels of patients undergoing spinal surgery during the beginning of anesthesia and during anesthesia are controlled by an anesthetist.

Category
Treatment - Other

2

Description
In the second intervention group, patients who are ready for spinal surgery from two days before surgery, during anesthesia and one day after surgery, will be under strict control of blood glucose with insulin protocol to maintain it in the range of 100 to 140 0 mg/ dec.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza Hospital

Full name of responsible person
Mohammadali Khodaei

Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3427 6306

Email
khodaei_ali@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Farid Najafi

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3836 0014

Email
fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Kermanshah University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Mohammadali Khodaei

Position
Resident of Neurosurgery

Latest degree
Medical doctor

Other areas of specialty/work
Neurosurgery

Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3427 6306

Email
khodaei_ali@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Hamidreza Saeidi

Position
Faculty Member of Kermanshah University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3836 7990

Email
H-R-SAEdi@YAHOO.COM

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person

Mohammadali Khodaei
Position
Resident Neurosurgery
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
khodaei_ali@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The main outcomes of the study will be shared.
When the data will become available and for how long
6 months
To whom data/document is available
If requested, results will be made available to other academic researchers
Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else
From where data/document is obtainable
To receive the documentation, email send for update manager
What processes are involved for a request to access data/document
In a 15-day period, the documents will be sent e-mail
Comments