

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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 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 tilt

## 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

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**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

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**Postal code**

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## 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

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H-R-SAEI@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

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**Province**

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**Postal code**

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**Phone**

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**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**