

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparisson of the effect of preoperative intravenous desmopressin on postoperative and during operation blood loss in patients undergoing major spine surgery

Protocol summary

Study aim

Examine the effect of desmopressin injection on volume of intra and postoperative hemorrhage in major Scoliosis

Design

A randomized controlled clinical trial

Settings and conduct

This study was conducted in Shahid Rajaee Hospital in Qazvin. The candidate patients for major spine surgery are randomly assigned to one group in case of meeting inclusion criteria and then demographic form including name, height, weight, age, postoperative hemorrhage, number of bloody gauzes (each gas between 30 and 50 ccs), blood in drain after surgery and the amount of required blood for injection are registered. The desmopressin injection procedure is as follows: 0.3 mg / 1 kg of body weight in injected. Surgeon name and operation duration are also registered. After Patient transfer, drain blood is registered for 24 h. in this study, no one is aware of randomization procedure and the patient group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The patient has Degenerative lumbosacral, 2. Patients consent. Exclusion criteria: 1. chronic heart disease, 2. Polydipsia. 3- congestive heart failure. 4. Hyponatremia. 5. Moderate to severe renal failure

Intervention groups

The intervention group includes people with Degenerative lumbosacral which are randomly assigned to this group and were delivered desmopressin and intra and postoperative hemorrhage was measured. The control group includes people with Degenerative lumbosacral which are randomly assigned and delivered placebo (normal saline) and intra and postoperative hemorrhage was measured.

Main outcome variables

evaluation Bleeding rate,Need for blood transfusion, rate

of bleeding, duration of operation in patients, duration of hospitalization in patients in placebo and drug groups It doesn't matte

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191221045840N1**

Registration date: **2020-01-20, 1398/10/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-20, 1398/10/30**

Update count: **0**

Registration date

2020-01-20, 1398/10/30

Registrant information

Name

Mahsa Vafaemastanabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 4770

Email address

mahsa.92vafaee@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparisson of the effect of preoperative intravenous desmopressin on postoperative and during operation blood loss in patients undergoing major spine surgery

Public title

Study of the effect of desmopressin injection on intraoperative hemorrhage of lumbar disc herniation
Outcome variable

Purpose

Basic scienece

Inclusion/Exclusion criteria**Inclusion criteria:**

thoracolumbosacral fracture degenerative lumbosacral disease hypertension & coagulation disorders all types of traumatic patient Consent to enter the research project

Exclusion criteria:

acute heart disease polydipsia chronic heart failure hypothermia chronic kidney disease & end stage renal disease

Age

No age limit

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **55**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method was used to generate random numbers between 0 and 1 in the software. if the number was above 0.5, the patient is in the intervention group (DDAVP) and if it was below 0.5, he is in the Placebo group. (normal saline).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the sealed envelopes numbered by a predetermined random list are used.in this study, no one including drug delivery nurse, Anesthesiology resident and the person filling the form and surgeons and the person responsible for data analysis is aware of randomization procedure and the patient group.

Placebo

Used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Committee of Qazvin University of Medical Sciences

Street address

Third floor, No. 80, Radouz-e-Rad (1/4) St., Pirouzeh Street, Fatemeh Square, Tehran-Iran

City

tehran

Province

Tehran

Postal code

1431634644

Approval date

2019-12-23, 1398/10/02

Ethics committee reference number

ir.qums.rec.1398.134

Health conditions studied**1****Description of health condition studied**

lumbosacral disc herniation

ICD-10 code

M51.37

ICD-10 code description

Other intervertebral disc degeneration, lumbosacral region

Primary outcomes**1****Description**

In this study, the main variable is intra and postoperative hemorrhage

Timepoint

From operation until 24 hours after the operation

Method of measurement

In this study, the intraoperative hemorrhage in Drain and the amount of Gauze consumed was measured and counted in the operating room (each Gauze is equal to 30-50 cc). also, the blood in the drain was measured until 24 hours.

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: DDAVP drug delivered group was desmopressin. Vasopressin Analogue increased Willebrand factor 8. The injected drug was used in this study. The dose of each Ampoule is 4mg / 1 ml. required dose for the patient is 0.3 mg/1 kg of body weight which is poured into 100 ccs normal saline and was injected 10 min during induction. The operation procedure: for all patients the standard technique for lumbar disc surgery provided by 2 surgeons. All patients have a drain for 24 hours

Category

Treatment - Drugs

2

Description

Control group: Placebo group: in this group, 100 ccs normal saline is Intravenously injected for 10 min during anesthesia. The operation procedure: for all patients the standard technique for lumbar disc surgery provided by 2 surgeons. All patients have a drain for 24 hours

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital of Qazvin

Full name of responsible person

Mahsa Vafaei Mastan Abad

Street address

Tehran, Third Floor, No. 80 Rad Radon (1/4) Street, Pirouzeh Street, Jihad Street (Fatemi Street)

City

tehran

Province

Tehran

Postal code

1431634644

Phone

+98 21 3327 2257

Fax

Email

mahsa.92vafaei@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

amir peymani

Street address

80th Floor No. 80 Rad Road, Pirouzeh St, Fatemi St, Tehran, Iran

City

tehran

Province

Tehran

Postal code

1431634644

Phone

+98 21 3327 2257

Email

mahsa.92vafaei@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

ali alizadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Qazvin- Bahrar Boulevard- Qazvin University of Medical Sciences

City

qazvin

Province

Tehran

Postal code

1431634644

Phone

+98 21 3327 2257

Email

mahsa.92vafaei@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
ali alizadeh

Position
associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Qazvin- Bahonar Boulevard- Qazvin University of
Medical Sciences

City
tehran

Province
Tehran

Postal code
1431634644

Phone
+98 21 3327 2257

Email
mahsa.92vafae@yaho.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
ali alizadeh

Position
Associate professor

Latest degree

Specialist

Other areas of specialty/work
Anesthesiology

Street address
qazvin

City
qazvin

Province
Tehran

Postal code
1431634644

Phone
+98 21 3327 2257

Email
mahsa.92vafae@yaho.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available