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 Vafaeemastanabad

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 Vafaee Mastan Abad

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
amir peymani

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

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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

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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