Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Desmopressin on The Post Operative Bleeding in Patients Undergoing Open Heart Surgery

Protocol summary

Study aim
Reduced postoperative bleeding in open heart surgery patients

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 194 patients.

Settings and conduct
All patients undergoing open heart surgery will be included in the study, according to a specialist in cardiovascular surgery. An expert who will be responsible for measuring bleeding will be blinded in terms of knowledge of the type of medication. Desmopressin and Sodium Chloride 0.9 sprays are given by the anesthesiologist in the operating room 30 minutes before the operation at a rate of 0.3 micrograms per kilogram, respectively, to each patient in the intervention and control group. The person giving the medicine in the operating room and the person who measures the patient's bleeding in the ICU OH section are the same for both groups and do not know what group the patient is in and what medication he has received

Participants/Inclusion and exclusion criteria
All patients are candidates for open heart surgery subject to informed consent Conscious dissatisfaction

Intervention groups
The intervention group will receive 0.3 micrograms per kilogram of desmopressin half an hour before the start of surgery. The control group will receive 0.3 micrograms per kilogram of 0.9 sodium chloride half an hour before the start of surgery.

Main outcome variables
Postoperative bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200424047185N1**
Registration date: **2020-05-26, 1399/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-26, 1399/03/06**
Update count: **0**

Registration date
2020-05-26, 1399/03/06

Registrant information

Name
Hamed Kiani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3328 4340

Email address
kianihamed93@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Desmopressin on The Post Operative Bleeding in Patients Undergoing Open Heart Surgery

Public title
The Effect of Desmopressin on The Post Operative Bleeding

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for open heart surgery
Exclusion criteria:
Blood coagulation disease
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **194**
Randomization (investigator's opinion)
Randomized
Randomization description
Easy (available) sampling, in which two groups of age and sex will be matched and matched frequently using stratified randomization. The explanation of this method is that after entering the study, patients are divided into two groups, male and female, which in each group of patients are divided into two categories of patients under 50 years of age and over 50 years of age. Depending on the accident, individuals will be assigned to two intervention groups and a control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
An expert who will be responsible for measuring bleeding reduction will be blinded in terms of knowledge of the type of medication. Desmopressin and normal saline sprays are given to each of the patients in the intervention or control group 30 minutes before the operation, respectively, by the anesthesiologist in the operating room 30 minutes before the start of the operation. The pharmacist and the person measuring the patient's bleeding at ICUOH are the same for both groups and do not know what group the patient is in and what medication he or she has received (they are blind).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Dr. Hesabi Square, Medical Sciences Campus
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2020-04-21, 1399/02/02
Ethics committee reference number
IR.ZAUMS.REC.1399.027

Health conditions studied

1

Description of health condition studied
Bleeding - open heart surgery - Desmopressin
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Postoperative bleeding
Timepoint
Measure the patient's bleeding rate two, six, eight, twelve, and twenty-four hours after surgery
Method of measurement
The amount of blood in the Chest Bottle is in milliliters

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Desmopressin is an artificial analogue of vasopressin group. 0.3 micrograms per kilogram is given to each patient of the intervention group 30 minutes before the operation.
Category
Treatment - Surgery

2

Description
Control group: Sodium chloride solution is 0.9% injectable, a sterile, non-febrile solution, free of preservatives and isotonic, and contains 9 mg of sodium chloride per ml. 0.3 micrograms per kilogram is given to each patient in the control group.
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ibn Abi Talib Hospital
Full name of responsible person
Azadi Ahmad Abadi Changiz
Street address
Salamat Blvd - Persian Gulf Highway
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
AzadiAhmad Abadi Changiz
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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
Zahedan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Azadiahmadabadi Changiz
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Heart surgery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available