Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Randomized Placebo-controlled trial of the effect of intranasal administration of desmopressin acetate on the bleeding complications after renal needle-biopsy sampling in patients with normal renal function

Protocol summary

Study aim

Determining the effect of intranasal desmopressin on the bleeding complications after renal biopsy

Design

Phase 3, Two arm, parallel-group , double-blind, randomized controlled trial on 60 subjects

Settings and conduct

Nephrology ward of Nemazee hospital was the location. We will enroll patients who are referred to Nemazee hospital's nephrology ward for elective renal biopsy. The patients who fill the consent form and are at least 16 years old will be considered. The researcher, the person who performs the biopsy, the nurses who administer the sprays, and the patients will be blinded about the type of treatments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients referred for renal biopsy. Non-inclusion criteria: abnormal renal function.

Intervention groups

The intervention group will receive high-concentration desmopressin spray nasally one hour before the renal biopsy. The control group will receive saline spray nasally one hour before the biopsy. The intervention group will receive high-concentration desmopressin spray nasally Octostim® (concentration of 150 micrograms per milliliter) (Ferring GmbH, Germany) one hour before the renal biopsy. The dose is dependent on the patient's weight; patients weighing less than 50 kilograms, 150 micrograms (one nasal spray) per dose; patients weighing more than 50 kg, 300 micrograms (two nasally sprays one per nostril) per dose. The control group will receive saline spray 0.65 percent nasally one hour before the biopsy (RINOSALTIN®, Sina Darou, Iran). The dose is dependent on the patient's weight; patients weighing less than 50 kilograms one nasal spray per dose; patients weighing more than 50 kg, two nasally sprays one per nostril per dose. The medication and the placebo are both prescribed once.

Main outcome variables

The proportion of patients who develop hematoma; The proportion of patients who develop hematuria.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201019049075N2**
Registration date: **2021-09-11, 1400/06/20**
Registration timing: **retrospective**

Last update: **2021-09-11, 1400/06/20**
Update count: **0**

Registration date

2021-09-11, 1400/06/20

Registrant information

Name

Shahrokh Ezzatzadegan Jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

shjahromi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-08-06, 1398/05/15

Actual recruitment start date

2019-04-27, 1398/02/07

Actual recruitment end date

2019-12-05, 1398/09/14

Trial completion date

2019-12-07, 1398/09/16

Scientific title

Randomized Placebo-controlled trial of the effect of intranasal administration of desmopressin acetate on the bleeding complications after renal needle-biopsy sampling in patients with normal renal function

Public title

Evaluation of the effect of intranasal desmopressin spray on complications of kidney biopsy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referred for renal biopsy.

Exclusion criteria:

Blood pressure more than 160/90 mmhg, Abnormal kidney function (serum creatinine more than 1.5 mg/dl and GFR less than 60 cc/min by CKD-EPI formula), Serum sodium less than 130 meq/liter, Taking anti-platelets or anticoagulants Thrombocytopenia History of kidney cancer Solitary kidney Small size kidneys Active urinary tract infection Abnormal prothrombin time

Age

From **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method in this study will be the permuted block technique. The permuted block technique randomizes patients between groups within a set of study participants, called a block. In this trial, which is performed on two groups with a 1:1 allocation ratio and a block size of 4, the total number of possible 4 permutations is equal to 6. If A is the label used for the intervention group and B for the placebo group, the possible blocks might be ABAB, BABA, AABB, BBAA, ABBA, BAAB. Then, using a table of random numbers and assigning the code zero to 9 to each of the permutations, a random list of 60 numbers, which includes 15 blocks of 4 (4 * 15 = 60 total number of samples), is generated and the order, in which each of the subjects is assigned to the two study groups, is determined. For example; AABB Code 0, BABA Code 1, AABB Code 2, BBAA Code 3, BAAB Code 4, and ABBA Code 5 to 9. Then, by using a table of random numbers, the starting point is randomly selected and 15 numbers are randomly chosen (in row or column) and the permutation assigned to each number is recorded. The order of placement of permutations will be from left to right, therefore, allocation of all 60 subjects to the two groups A and B will be determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study would be a double-blind trial. The principle investigator provides one of the research nurses with the randomization list of the assignment of individuals to the two groups. The nurse who randomly places patients into two groups is different from the nurse who prescribes medication. The labels of desmopressin sprays, as well as the placebos, are covered. Therefore, the lead researcher, the prescribing nurse, and the patients will not be informed of the allocation. The person evaluating the study will be completely different from the staff involved in the medication prescribing process. Therefore, the radiologist who performs the ultrasound is unaware of the patients' allocation. Only the statistician saw unblinded data.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, School of Medicine, Shiraz University of Medical Sciences

Street address

Vice Chancellor for Research, 3rd Floor, Building No.3, Shiraz Medical School, Imam Hossein Square, Zand St., Tel. No.: 07132349333

City

Shiraz

Province

Fars

Postal code

7193737485

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.SUMS.MED.REC.1398.054

Health conditions studied

1

Description of health condition studied

Bleeding

ICD-10 code

L76.22

ICD-10 code description

Postprocedural hemorrhage and hematoma of skin and subcutaneous tissue following other procedure

2

Description of health condition studied

Kidney biopsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The proportion of the patients who develop hematoma

Timepoint

24 hours after biopsy

Method of measurement

Ultrasound

2

Description

The proportion of the patients who develop hematuria.

Timepoint

24 hours after biopsy

Method of measurement

Urinalysis

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: The intervention group will receive high-concentration desmopressin spray nasally Octostim® (concentration of 150 micrograms per milliliter) (Ferring GmbH, Germany) one hour before the renal biopsy. The dose is dependent on the patient's weight; patients weighing less than 50 kilograms, 150 micrograms (one nasal spray) per dose; patients weighing more than 50 kg, 300 micrograms (two nasally sprays one per nostril) per dose.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive RINOSALTIN® nasal spray (0.65 percent saline spray) (Sina Darou, Iran) nasally one hour before the biopsy. The dose is dependent on the patient's weight; patients weighing less than 50 kilograms one nasal spray per dose; patients weighing more than 50 kg, two nasally sprays one per nostril per dose.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nemazee hospital

Full name of responsible person

Shahrokh Ezzatzadegan Jahromi

Street address

Nemazee hospital, Nemazee square, Zand st.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Web page address

https://research.sums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Shahrokh Ezzatzadegan Jahromi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All participants' personal data can be shared after de-identification.
When the data will become available and for how long
The start of the data access period can be immediately after the results are published.
To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

There is no more condition.

From where data/document is obtainable

By contacting the study presenter Shahrokh Ezzatzadegan, email shjahromi@sums.ac.ir

What processes are involved for a request to access data/document

After receiving the request by email, the data will be sent immediately.

Comments