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 renal failure

Protocol summary

Study aim

Determining the effect of intranasal administration of desmopressin acetate on reducing the bleeding complications after renal needle-biopsy sampling in patients with renal failure

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 biopsy, and the patients will be blinded about the type of treatments. Because the shape of normal saline sprays is different from desmopressin spray, the nurses who administer the sprays are aware of the allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients referred for renal biopsy
Exclusion criteria: serum creatinine equal or more than 2 mg/dL

Intervention groups

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: **IRCT20201019049075N1**
Registration date: **2021-08-10, 1400/05/19**
Registration timing: **retrospective**

Last update: **2021-08-10, 1400/05/19**
Update count: **0**

Registration date

2021-08-10, 1400/05/19

Registrant information

Name

Shahrokh Ezzatzadegan Jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4316

Email address

shjahromi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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 renal failure

Public title
Evaluation of the effect of intranasal desmopressin spray on the complications of kidney biopsy in renal failure
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred for renal biopsy.
Exclusion criteria:
Serum creatinine equal or more than 2 mg/dl 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 Patients who have received any kind of renal replacement therapy (hemodialysis or peritoneal dialysis) within the week before the biopsy Blood pressure more than 160/90 mmHg
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
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
2019-11-26, 1398/09/05
Ethics committee reference number
IR.SUMS.MED.REC.1398.481

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

3

Description of health condition studied
Acute kidney failure
ICD-10 code
N17.9
ICD-10 code description
Acute kidney failure, unspecified

Primary outcomes

1

Description
The proportion of the patients who develop hematoma.
Timepoint
24 hours post biopsy
Method of measurement
Ultrasound

2

Description
The proportion of the patients who develop hematuria.
Timepoint
24 hours post 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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Postal code
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Phone
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Email
shjahromi@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Abbas Rezaeianzadeh
Street address
Seventh Floor- Central Building of Shiraz University of Medical Sciences- Next to the Red Crescent - Zand St.
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+98 71 3212 2430

Email

vcrdep@sums.ac.ir

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

Internal Medicine

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Department of Internal Medicine, Nemazee Hospital, Nemazee Square, Zand street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

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Name of organization / entity

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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