Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Determination of the Preventive Effect of Desmopressin Acetate on the incidence of bleeding complications following kidney biopsy in patients with renal disease

Protocol summary

Study aim

Determining the preventive effect of desmopressin acetate on the occurrence of bleeding complications following renal biopsy in patients undergoing renal biopsy

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 120 patients. Excel software rand function was used for randomization

Settings and conduct

This study was a randomized clinical trial on 120 biopsy candidates referred to Golestan and Imam Hospitals of Ahvaz University of Medical Sciences. In this study, 60 patients received desmopressin and 60 patients received placebo. The study was performed as a double-blind study. In this way, the patients participating in the study and the treatment staff were unaware of the type of drug given to the participants in the study.

Participants/Inclusion and exclusion criteria

Exclusion criteria : Systrelic Blood Pressure Time Biopsy less than160mmhg Diastolic BP Time to do biopsy less than100mmhg Single kidney Kidney cancer Renal hydronephrosis Renal Pyrenophore Small size Significant kidneys in ultrasound Severe obesity Hemoglobin less than 11 Sodium concentration in serum less than 120 Primary phenotypes Renal transplantation Multiple cysts in both kidneys inclusion criteria: People 18 years and older 15≤GFR≤90 cc/min/1.73 m2 according MDRD formula

Intervention groups

Intervention group: In this group, 60 patients received 0.3 µg / kg desmopressin acetate (Ferring GmbH Keil, Germany) intranasally 1 hour before biopsy. Placebo group: In this group, 60 patients received 0.65% sodium chloride 1cc/kg (Raha Pharmaceutical Company) intranasally 1 hour before biopsy.

Main outcome variables

Kidney biopsy will be evaluated immediately after taking the sample and 24 hours after it and in case of hematoma 48-72 hours later by ultrasound.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090701002112N3**
Registration date: **2020-10-04, 1399/07/13**
Registration timing: **retrospective**

Last update: **2020-10-04, 1399/07/13**
Update count: **0**

Registration date

2020-10-04, 1399/07/13

Registrant information

Name

Ali Ghorbani

Name of organization / entity

Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date
2018-06-22, 1397/04/01
Actual recruitment end date
2020-01-25, 1398/11/05
Trial completion date
2020-05-23, 1399/03/03

Scientific title
Determination of the Preventive Effect of Desmopressin Acetate on the incidence of bleeding complications following kidney biopsy in patients with renal disease

Public title
Determination of the Preventive Effect of Desmopressin Acetate on the incidence of bleeding complications following kidney biopsy in patients with renal disease
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
People 18 years and older 15≤GFR≤90 cc/min/1.73 m2 according MDRD formula
Exclusion criteria:
Disrupted coagulation profile (including disruption in any of the PT tests, INR, PTT, and platelet counts are less than 50000 Systrelic Blood Pressure Time Biopsy less than160mmhg Diastolic BP Time to do biopsy less than100mmhg Single kidney Kidney cancer Renal hydronephrosis Renal Pyrenophore Small size Significant kidneys in ultrasound Severe obesity Hemoglobin less than 11 Sodium concentration in serum less than 120 Primary phenotypes Renal transplantation Multiple cysts in both kidneys
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **146**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were divided into two groups A and B. Block randomization methods were used. The size of the block was four and in each block 2 patient in group A and 2 patient in group B were assigned. The order of groups A and B within each block was determined randomly using function (RAND) in Excel software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and the interventionist and the person examining the results did not know what group the individuals were in, and the study would be double blind
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahwaz Jundishapur University of Medical Sciences (AJUMS)
Street address
Ahvaz Jndishapour University of Medical Sciences, Golestan blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
IR.AJUMS.REC.1394.264

Health conditions studied

1

Description of health condition studied
Chronic kidney patients
ICD-10 code
N18.9
ICD-10 code description
Chronic kidney disease, unspecified

Primary outcomes

1

Description
Hematoma
Timepoint
Immediately after receiving a kidney biopsy specimen and 24 hours later, and in the event of a hematoma, 48-72 hours later
Method of measurement
Ultrasonography

Secondary outcomes

1

Description
Hematuria
Timepoint
After biopsy
Method of measurement
View at any time urinating

2

Description
Vital signs l (blood pressure and heart rate)
Timepoint
Every 15 minutes for 2 hours, then every 1 hour for 4 hours, then every 2 hours for 6 hours, and then every 4 hours
Method of measurement
Device

3

Description
Flank pain
Timepoint
Follow up on every visit
Method of measurement
Physical exam

4

Description
Biochemical Factors (Sodium, Hemoglobin, Hematocrit)
Timepoint
24 hours after biopsy
Method of measurement
Blood test

Intervention groups

1

Description
Based on the block of redundancy and the patient in the intervention group, 1 hour before biopsy, desmopressin acetate is received in the nose and 1 kg / kg. After 1 hour, the ultrasound ultrasound radiologist will perform ultrasound with supine and needl
Category
Prevention

2

Description
Based on the rate of redundancy and the fact that the patient is in the control group, 1 hour before biopsy, 0.6 kg / kg sodium chloride receives intranasal. After 1 hour, the ultrasound ultrasound radiologist will perform ultrasound with supine and needl
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nephrology Department of Imam Khomeini Hospital and Ahvaz Golestan
Full name of responsible person
Dr Ali Ghorbani
Street address
Jundishapur University of Medical Sciences, olestan Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badavi
Street address
Ahvaz, Jundishapur University of Medical Sciences, Ahwaz, Golestan Blvd., Esfand Avenue
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Grant name
Ahwaz University of Medical Sciences
Grant code / Reference number
U-95038
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Ali Ghorbani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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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