Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of injectable transamine administration in reducing the volume of bleeding in open trans-vesicular prostatectomy in patients with benign prostatic hyperplasia

Protocol summary

Study aim
Determination of hemoglobin level to evaluate the volume of bleeding

Design
This study was a clinical trial with a control group, with parallel groups, single blind, randomized, phase 2 per 70 patients for randomization of the Excel function rand function.

Settings and conduct
This study: Determining the effectiveness of injectable transamine administration in reducing the volume of bleeding in open transvesical prostatectomy in patients with benign prostatic hyperplasia Time: in 2021 Location: In the urology clinic of Al-Zahra Hospital affiliated to Isfahan University of Medical Sciences Done. Blinding: A type of clinical trial with a control group, with parallel groups, one-way blind so that only the participant does not know about the drug, randomized, phase 2 on 70 patients was used to randomize the rand function of Excel software. Then 35 patients in the case group underwent injectable transamine (1 gram intraoperatively and 48 hours after surgery, 3 times a day injection) and 35 patients in the control group underwent placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients undergoing prostatectomy. Exclusion criteria: Use of anticoagulants such as aspirin and dipyridamole And any history of thrombotic events

Intervention groups
The control group was treated with placebo and the case group was treated with injectable transamine (1 gram intraoperatively and 48 hours postoperatively, 3 times daily)

Main outcome variables
Hemoglobin level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211121053127N1**
Registration date: **2021-12-21, 1400/09/30**
Registration timing: **prospective**

Last update: **2021-12-21, 1400/09/30**
Update count: **0**

Registration date
2021-12-21, 1400/09/30

Registrant information

Name
Sina Mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3796 2730

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sina.mhmd1374@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of injectable transamine administration in reducing the volume of bleeding in open trans-vesicular prostatectomy in patients with benign prostatic hyperplasia

Public title
Efficacy of injectable transamine in patients with benign prostatic hyperplasia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing Prostatectomy Patients who are willing to participate in the study

Exclusion criteria:
Use of anticoagulants such as aspirin and dipyridamole Prothrombin time and partial thromboplastin time are high for whatever reason Any history of thrombotic events History of bleeding disorders Chronic kidney disease (serum creatinine greater than 180 micromoles per liter).

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will be performed blindly with a simple randomization method using Excel software. Random function of Excel software based on patient file number will be used for randomization. Patients with benign prostatic hyperplasia entered the Excel program based on the file number and were divided into case and control groups based on the random button. There were two groups of 35 people in total. By entering the file number in Excel program, then the random number is selected from the data analysis command. This study has 2 groups that can be numbered from 1 to 2, respectively. We also want 35 people in each group. As a result, sequences 1 to 2 should be repeated 35 times each time. It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 35 for repeating the sequence. In this way, 70 units will be produced.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the patient did not know whether she was in the injectable transamine group or in the placebo group. In the placebo group, distilled water or normal saline is injected instead of medicine Which is similar in shape, color, state, smell and in every way, similar to medicine

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jerib St., Shiraz Gate

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-08-13, 1400/05/22

Ethics committee reference number
IR.MUI.MED.REC.1400.374

Health conditions studied

1

Description of health condition studied
Benign prostate enlargement

ICD-10 code
D29.1

ICD-10 code description
Benign neoplasm of prostate

Primary outcomes

1

Description
Bleeding volume

Timepoint
24 hours after surgery

Method of measurement
The amount of ml of blood removed from the patient's body

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injectable transamine * Quantity: (1 gram injection during surgery and 48 hours after surgery, 3 times a day injection) After induction of anesthesia, transamine 10 mg per kg will be infused for 10 minutes * Content: Transamine * Duration of treatment: 48 hours after surgery * Chemical composition: Pay attention to the drug leaflet in the box. * Consumption dose: 1 gram * How to use: injection * Manufacturer: Razi

Category
Treatment - Drugs

2

Description
Control group: Plasibo (In the placebo group, distilled water or normal saline is injected instead of medicine.) 1 gram of injection during the operation and 48 hours after the operation, 3 times a day injection * Content: Plasibo in terms of color, shape, volume, condition, odor. ... is similar to the main drug * Duration of treatment: 48 hours after surgery ** Dosage: 1 gram * How to use: injection * Manufacturer: Razi

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Educational and Medical Center

Full name of responsible person
Mehrdad Mohammadi sichani

Street address
Al-Zahra Educational and Medical Center, Sofeh Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
20

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
Esfahan University of Medical Sciences

Full name of responsible person
Mehrdad Mohammadi sichani

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Urology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
There is 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