

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Effect of ARISTA Hemostatic Powder on Reduction of Complications after PCNL Surgery

Protocol summary

Study aim

Effect of ARISTA Hemostatic Powder on Reduction of Complications after PCNL(Percutaneous Nephrolithotomy)Surgery

Design

Clinical trial with two parallel groups without blinding ,simple randomization

Settings and conduct

This clinical trial will be performed in Sina Hospital. Patients will be divided into control and intervention groups by simple randomization method. Before surgery, for all patients KUB will be performed. In the intervention group, after surgery, the Arista powder will be pumped into the amplutz before removal of the amplutz followed by its removal in the amplutz route. This study was not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria:A candidate for treatment in the form of PCNL Exclusion criteria:Coagulation problems,Pregnant women

Intervention groups

1-Hemostatic Powder:The powder in the intervention group will be used to determine the extent of bleeding and surgical complications 2-No use of hemostatic powder :The control group will not use hemostatic powder

Main outcome variables

Evaluation of bleeding after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N2**

Registration date: **2019-09-07, 1398/06/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-07, 1398/06/16**

Update count: **0**

Registration date

2019-09-07, 1398/06/16

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-06, 1398/06/15

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ARISTA Hemostatic Powder on Reduction of Complications after PCNL Surgery

Public title

Effectiveness of bleeding preventive powder for reducing postoperative PCNL complications

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for PCNL treatment

Exclusion criteria:

Patients with blood coagulation defects Patients with acute urinary tract infections Pregnant women Very obese people

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method used in this study will be a simple randomization study that randomly selects a number using the random number table and moves to the right according to the previous assumption. If the number was even, the patient entered the intervention group and if Number of individual patients will enter the control group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs-Tehran University of Mwdical Sciences

Street address

Emam Khomeini St,Hassan-abad Sq,Sina Hospital,Urology Research Center

City

Tehran

Province

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Postal code

1136746911

Approval date

2019-06-24, 1398/04/03

Ethics committee reference number

IR.TUMS.VCR.REC.1398.347

Health conditions studied

1

Description of health condition studied

Urinary stones

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney with calculus of ureter

Primary outcomes

1

Description

Bleeding after surgery from the site of surgery

Timepoint

Immediately after surgery

Method of measurement

The number of wet gases

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Half of Patients undergoing PCNL surgery after the end of surgery and removal of stones and re-examination of the kidney with a nephroscope before removing the ampluvat of the hemostatic powder (3 grams with brand name (arista is pumped into the amplitz and accompanied by the exit of the amplitz in its path) The hemostatic powder is pumped

Category

Treatment - Drugs

2

Description

Half of patients will undergo PCNL surgery that will not receive ARISTA hemostatic powder after surgery.receive ARISTA after the surgery.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Behroz Fatahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tehran 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
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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