

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of *Urtica dioica* extract on short-time consequences of double-J ureteral catheters

Protocol summary

Summary

The aim of the study: the effect of the extract of nettle on short-term outcomes ureteral double J catheter. The design of the study: randomized, double-blind, placebo controlled, single-center, phase 1-2 trial. The study population: all patients 20 to 70 years old following the lithotripsy for ureteral double J catheter is embedded. The main criteria for inclusion: stone size (lesser than ten mm) and place the stone below the junction (ureteral pelvic). Exclusion criteria: previous surgery on the bladder or lower urinary tract; active urinary tract infection; lack of proper placement of the double J catheter. Sample size: 62. Case study: urtidin pills (nettle extract) essential pharmaceutical company Barij a dosage of one pill every 8 hours for fifteen days. Intervention time: urtidin pills with a dosage of one tablet every 8 hours for a period of fifteen days it will be given to the intervention group. The outcome of the study: 1. Dysuria; 2- frequency; 3. hematuria, with starting at least 24 hours after surgery; 4. pain in the flank area; 5. Urinary Tract Infection; 6. Fever; 7. mucosal inflammation of the bladder and ureter.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090329680N1**
Registration date: **2017-03-18, 1395/12/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-18, 1395/12/28

Registrant information

Name

Saeed Heydari

Name of organization / entity

Shahroud University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahroud University of Medical Sciences

Expected recruitment start date

2017-03-10, 1395/12/20

Expected recruitment end date

2017-07-11, 1396/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Urtica dioica* extract on short-time consequences of double-J ureteral catheters

Public title

The effect of *Urtica dioica* exstract on consequences of double-J ureteral catheters

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the size of the stone and the location of the stone which measures (less than ten mm) and place the stone below the junction (urethral pelvic); patients suffering a urethral stone, just on one side and those who bilateral urethral stones or kidney stones are excluded; age between 20-70 years old(due to a higher

incidence of kidney stones in this age range); no history of urologic manipulation in the past few years is a another criteria. Exclusion criteria: history of benign prostatic hypertrophy; previous surgery on the bladder or lower urinary tract; bladder stones; active urinary tract infection; lack of proper placement of the double j catheter; neurogenic bladder and the lack of the next visit.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sharoud University of Medical Sciences

Street address

Sharoud University of Medical Sciences, 7th Tir square

City

Shahrour

Postal code

3613773955

Approval date

2015-12-22, 1394/10/01

Ethics committee reference number

IR.SHMU.REC.1394.145

Health conditions studied

1

Description of health condition studied

Complications of double j urethral cathater

ICD-10 code

T83

ICD-10 code description

Complications of genitourinary prosthetic devices, implants and grafts

Primary outcomes

1

Description

gross hematuria

Timepoint

3 and 7 days after start of treatment

Method of measurement

questionnaire

2

Description

dysuria

Timepoint

3, 7 and 15 days after start of treatment

Method of measurement

questionnaire

3

Description

frequency

Timepoint

3, 7 and 15 days after start of treatment

Method of measurement

questionnaire

4

Description

pain

Timepoint

3, 7 and 15 days after start of treatment

Method of measurement

VAS score

5

Description

microscopic hematuria

Timepoint

15 days after start of treatment

Method of measurement

urine analysis

6

Description

edema and inflammation of the mucus of bladder and ureter

Timepoint

15 days after start of treatment

Method of measurement

cystoscopy

7

Description

urinary infection

Timepoint

15 days after start of treatment

Method of measurement

urine culture

8

Description

fever

Timepoint

3, 7 and 15 days after start of treatment

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The control group patients after discharge - the day after surgery - and for a period of 48 hours, antibiotic cefixime 400, on a daily basis and 10 ibuprofen housing 400, one pill, given every 8 hours.

Category

Treatment - Drugs

2

Description

In the intervention group, in addition to these drugs, pills urtidin pharmaceutical barij company, a dosage of one pill every 8 hours, for a period of fifteen days it will be given.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology clinic or Emergency Department of Emam Hossein Hospital

Full name of responsible person

Saeed Heydari

Street address

Emam Hossein Hospital

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sharoud University of Medical Sciences

Full name of responsible person

Hassan Emamian

Street address

Sharoud University of Medical Sciences, 7th Tir square

City

Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sharoud University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Clinical Research Development, Sharoud University of Medical Sciences

Full name of responsible person

Saeed Heydari

Position

Medical student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Sharoud University of Medical Sciences

Full name of responsible person

Naser Mogharabian

Position

Urologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty