# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparison effect of leaf of Biarum carsuchrum and oral tamsulosin on pain improvement and passage rate of renal and ureteral stones sized 4-10 millimeter

## Protocol summary

**Study aim**

Comparison effect of Biarum carsuchrum leaf and tamsulosin on pain improvement and passage of renal and ureteral stones sized 4-10 millimeter

**Design**

In this randomized, parallel group clinical trial from January 2019 to December 2019 with simple sampling methods eighty (80) patients older than 18 years old allocated in one of two groups (Biarum carsuchrum leaf or tamsulosin) and will received intervention for two weeks.

**Settings and conduct**

Patients referring to Shahid Mofateh clinic of Yasuj suffering from renal or ureteral stones with sizes of 4-10 millimeter allocated in one of two groups with simple sampling method. The history and physical exam and basic serum samples will be checked. In two groups it is recommended to walk and do exercise at least 30 minutes per day .Two weeks and one month later, the patients will be re-examined and KUB or ultrasonography would be performed and the success of treatment was measured and recorded according to the size of the stone and the presence of residual stones. Also pain severity of patients will be checked and recorded by Visual analogue scale (VAS) during treatment and two weeks after that.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria:Age more than18 years old suffering from renal or ureteral stone less than 10 millimeter, having informed consent form Exclusion criteria:Uncontrolled coagulopathy , Pregnancy, Azotemia, Allergy to medical or herbal drugs, Severe cardiovascular or pulmonary disease

**Intervention groups**

Intervention group:Biarum carsuchrum leaf in form of capsule will prepare and prescribed in divided dosage of 3 capsule of 300 mg per day after meal with one glass of water for two weeks. Control group: Tamsulosin capsule 0.4 mg will prescribe every night with one glass of water for two weeks.

**Main outcome variables**

Change in the size and passage of stones ؛ pain severity

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20081011001323N21**
Registration date: **2019-02-07, 1397/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-07, 1397/11/18**
Update count: **0**

**Registration date**

2019-02-07, 1397/11/18

**Registrant information**

**Name**

Sadrollah Mehrabi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 74 3334 6070

**Email address**

dr.mehrabi@yums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-01-30, 1397/11/10

**Expected recruitment end date**

2019-12-01, 1398/09/10

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

**Scientific title**
Comparison effect of leaf of Biarum carsuchrum and oral tamsulosin on pain improvement and passage rate of renal and ureteral stones sized 4-10 millimeter

**Public title**
Comparison effect of Biarum carsuchrum and tamsulosin on urinary stones
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age more than18 years old Suffering from renal or ureteral stone less than 10 millimeter Having informed consent form
**Exclusion criteria:**
Uncontrolled coagulopathy Pregnancy Azotemia Allergy to medical or herbal drugs Severe cardiovascular or pulmonary disease
**Age**
From **18 years** old to **99 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients are allocated with simple sampling methods and random numbering table to one of each group and received the intervention of that 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**
Ethics committee of Yasuj University of Medical Sciences
**Street address**
Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
7591741417
**Approval date**
2019-01-27, 1397/11/07
**Ethics committee reference number**
IR.YUMS.REC.1397.130

## Health conditions studied

**1**

**Description of health condition studied**
Calculus of kidney and ureter
**ICD-10 code**
N20.2
**ICD-10 code description**
Calculus of kidney with calculus of ureter

## Primary outcomes

**1**

**Description**
Passage of renal and upper ureteral stones with sizes from 4-10 millimeter
**Timepoint**
Two weeks and one month after start of treatment
**Method of measurement**
Taking KUB and Ultrasonography and report of patients

**2**

**Description**
Pain severity score due to passage of stones
**Timepoint**
During study and two weeks and one month after start of treatment
**Method of measurement**
With Visual Analogue Scale(VAS)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Biarum carsuchrum leaf in form of capsule will prepare and prescribed in divided dosage of 3 capsule of 300 mg per day after meal with one glass of water for two weeks.
**Category**

Treatment - Drugs

**2**

**Description**
Control group: Tamsulosin capsule 4 mg / day is prescribed with a glass of water every night for two weeks.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Mofateh clinic of Yasuj
**Full name of responsible person**
Sadrolleh Mehrabi
**Street address**
Shahid Mofateh clinic, Montazeri street,Yasuj,Iran
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mehrabi.sadrollah@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Yasouj University of Medical Sciences
**Full name of responsible person**
Ali Mousavizadeh
**Street address**
Yasuj, Motahari St., Yasuj University of Medical Sciences, Research Deputy
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7591741417
**Phone**
+98 74 3334 6074
**Email**
health.epid@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Yasouj 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**
Yasouj University of Medical Sciences
**Full name of responsible person**
Yasouj University of Medical Sciences
**Position**
Professor, Chairman of Urology Department, Yasuj University of Medical Sciences
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Urology
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## Person responsible for scientific inquiries

**Contact**
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Sadrollah Mehrabi
**Position**
Professor, Fellowship of endourology and laparoscopy
**Latest degree**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Sadrollah Mehrabi

**Position**

Professor, Fellowship of endourology and laparoscopy

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

**Street address**

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**Postal code**

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**Email**

dr.mehrabi@yums.ac.ir

## 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 further 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