

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of cherry concentrate (*Prunus cerasus*) and polycitrate on the number and size of urinary stones in children aged one to eighteen years old

#### Protocol summary

##### Study aim

Effect of *Prunus cerasus* on nephrolithiasis improvement in children

##### Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 3 on 60 patients. The random number table was used for randomization.

##### Settings and conduct

The field of the study is Dr Sheikh hospital affiliated to Mashhad University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 1-18 years with nephrolithiasis. Non inclusion criteria: Metabolic disorders including hyperuricosuria, hypercalciuria, hyperoxaluria, cyctinuria, hypocitraturia

##### Intervention groups

Control group reciving polycitrate one miligram per kilogram body weight. Intervention group reciving *Prunus* concentrate 1.5 miligram per kilogram body weight.

##### Main outcome variables

Number and size of stones

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170415033428N5**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **prospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

##### Registration date

2020-06-29, 1399/04/09

##### Registrant information

##### Name

Elham Bakhtiari

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3727 3943

##### Email address

bakhtiarie@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2021-05-22, 1400/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of cherry concentrate (*Prunus cerasus*) and polycitrate on the number and size of urinary stones in children aged one to eighteen years old

##### Public title

Effect of *Prunus cerasus* on nephrolithiasis in children

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

children aged 1-18 years with nephrolithiasis

##### Exclusion criteria:

metabolic disorders including hyperuricosuria,

hypercalciuria, hyperoxaluria and cystinuria and hypercaturia

#### Age

From **1 year** old to **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple personal randomization will be done using random numbers table and [www.randomization.com](http://www.randomization.com) website. Randomization concealment will be done using closed envelopes. The envelopes will be prepared and printed by one of the members of the research team and random numbers with the help of [Randomaization.com](http://Randomaization.com) and will be placed inside the envelope. The envelopes are closed and the contents cannot be seen from the outside. Then, the purpose of the study will be explained to the person who meets the inclusion criteria and if the person wishes and signs the informed consent form, takes an envelope and then opens it and enters the intervention or control group based on the contents of the envelope.

#### 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 Mashhad University of Medical Sciences

##### Street address

Dr Sheikh hospital, Gharanee Blvd

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

456789

#### Approval date

2017-09-27, 1396/07/05

#### Ethics committee reference number

IR.MUMS.FM.REC.1396.376

## Health conditions studied

### 1

#### Description of health condition studied

urolithiasis

#### ICD-10 code

N20

#### ICD-10 code description

Calculus of kidney and ureter

## Primary outcomes

### 1

#### Description

Size of nephrolithiasis (urinary stones)

#### Timepoint

Before intervention and two months after intervention

#### Method of measurement

Sonography

## Secondary outcomes

### 1

#### Description

Number of stones

#### Timepoint

Before intervention and two months after intervention

#### Method of measurement

Sonography

## Intervention groups

### 1

#### Description

Intervention group: Cherry concentrate contains Melatonin made by Khoshe-sorkh Shargh Company, 1.5 cc per kg body weight orally, once daily for two months

#### Category

Treatment - Drugs

### 2

#### Description

Control group: poly citrate made by Sepidaj pharmaceutical Company, 1 cc per kg body weight orally, once daily for two months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dr Sheikh hospital

##### Full name of responsible person

Elham Bakhtiari  
**Street address**  
Gharani Blvd  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
456789  
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Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Pharmacology  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Elham Bakhtiari  
**Street address**  
Gharani Blvd  
**City**  
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**Province**  
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**Email**  
Bakhtiarie@mums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Mashhad 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**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Elham Bakhtiari  
**Position**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Elham Bakhtiari  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Pharmacology  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Elham Bakhtiari  
**Position**  
Assistant professor  
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**Email**

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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