

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 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 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
Phone
+98 51 3727 3943
Email
Bakhtiarie@mums.ac.ir

Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Pharmacology
Street address
Gharani Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
456789
Phone
+98 51 3727 3943
Email
Bakhtiarie@mums.ac.ir

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
Mashhad
Province
Razavi Khorasan
Postal code
456789
Phone
+98 51 3727 3943
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
Street address
Gharani Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
456789
Phone
+98 51 3727 3943
Email
Bakhtiarie@mums.ac.ir

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
Latest degree
Ph.D.
Other areas of specialty/work
Pharmacology
Street address
Gharani Blvd
City
Mashhad

Province

Razavi Khorasan

Postal code

456789

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+98 51 3727 3943

Email

Bakhtiarie@mums.ac.ir

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