Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 hypercitaturia

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

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
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 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
Phone
+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