Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Boron supplement on severity and duration of colic pain and the time of expulsion of urinary stone after Extracorporeal Shock Wave Lithotripsy compared to Tamsulosin

Protocol summary

Study aim
Determination of the effect of Boron supplement on stone expulsion rate after extra corporeal shock wave lithotripsy compared with tamsulosin

Design
Clinical trial with control group,parallel groups, single blinded, randomised

Settings and conduct
Patients over 18 years old after ESWL and filling out an informed consent form will include in the study. we assessed height and weight, medications and previous illness history of participants. Then Patients randomly will treat with Boron supplement (10 mg/BD) or Tamsulosin (0.4 mg/day) for 14 days . Recommendations for increase fluid intake and use analgesics (NSAIDs) if needed were given to patients. Patients will comeback with ultra- sonography or KUB two weeks after the intervention. Questionnaires regarding stone expulsion rate, stone expulsion time, patient's pain severity according to VAS scale, drug side effects, and the number of used analgesic were completed in addition to the assessment of serum creatinine and urine analysis.

Participants/Inclusion and exclusion criteria
Patients over 18 years of age referred to the Extracorporeal Shock Wave Lithotripsy section of the Labbafinejad Clinic who did not have urinary tract infection or chronic kidney disease and had no history of urinary tract surgery (PCNL or open stone). They also do not have contraindications to ESWL, including pregnancy and unmodified coagulopathy, and do not have estrogen-dependent cancers (breast, endometrial, and ovarian). The lactated women were not included in the study.

Intervention groups
Adults more than 18 years of old after ESWL treated with Boron supplement 10 mg/BD (sodium tetraborate decahydrate; Sigma, St. Louis, USA) in intervention group or with CapTamsulosin 0.4 mg/every night (Tasnim pharmaceutical Co.) in control group

Main outcome variables
The remained stone size, stone expulsion time and the patient's pain severity (according to VAS scale)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191026045244N3**
Registration date: **2022-04-11, 1401/01/22**
Registration timing: **retrospective**

Last update: **2022-04-11, 1401/01/22**
Update count: **0**

Registration date
2022-04-11, 1401/01/22

Registrant information

Name
Maryam Taheri

Name of organization / entity
Urology and Nephrology Research Center,Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-05, 1397/01/16

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2018-04-05, 1397/01/16

Actual recruitment end date

2019-12-01, 1398/09/10

Trial completion date

2020-03-05, 1398/12/15

Scientific title

The effect of Boron supplement on severity and duration of colic pain and the time of expulsion of urinary stone after Extracorporeal Shock Wave Lithotripsy compared to Tamsulosin

Public title

The effect of Boron supplement on severity and duration of colic pain and the time of expulsion of urinary stone after Extracorporeal Shock Wave Lithotripsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

kidney stone patients referred to urinary stone Extracorporeal Shock Wave Lithotripsy of Labbafi nejad clinic

Exclusion criteria:

Urinary Tract Infection Chronic Kidney Disease Urinary Tract Surgery history (PCNL or open stone) contraindications to extracorporeal shockwave lithotripsy (ESWL) include: Acute urinary tract infection or urosepsis, Uncorrected bleeding disorders or coagulopathies, Pregnancy. History of Estrogen-Dependent Cancer (Breast, Endometrial and Ovarian) pregnancy or lactation

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **160**

Actual sample size reached: **266**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with the block size of four was used, to randomly allocate the patients to Boron and Tamsulosin groups and balance patient allocation between groups. Random Allocation software was used to generate random sequences. Given the random sequences generated, patients were divided into two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

According to the apparent difference between tamsulosin (14 capsule) and boron (28 capsule) appearance and the numbers of drug needed in two groups, both participants and care provider not blinded during the study. But in the data analysis phase, data analyzer colleague was blinded regarding the type of drug prescribed in two patients group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

The effect of Boron supplement on severity and duration of colic pain and the time of stone expulsion of urinary stone after extra corporeal shock wave lithotripsy compared to Tamsulosin

Secondary trial Id

46805

Registration date

2020-07-30, 1399/05/09

Ethics committees

1

Ethics committee

Name of ethics committee

Urology Nephrology Research Center

Street address

Pasdaran

City

Tehran

Province

Tehran

Postal code

1666665111

Approval date

2017-08-10, 1396/05/19

Ethics committee reference number

46805: IR.SBMU.UNRC.1395.74

Health conditions studied

1

Description of health condition studied

kidney stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Stone size

Timepoint
Before ESWL and 14 days after ESWL
Method of measurement
The size of the stone in millimeters reported in the patient's ultrasound

2

Description
Pain of expulsion
Timepoint
14 days after ESWL
Method of measurement
Visual Analogue Scale

3

Description
Time of expulsion
Timepoint
14 days after ESWL
Method of measurement
Questionnaire

4

Description
Auxillary treatment after ESWL
Timepoint
14 days after ESWL
Method of measurement
Questionnaire

5

Description
drug complications
Timepoint
14 days after ESWL
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Number of pain medicines used
Timepoint
14 days after ESWL
Method of measurement
questionnaire

2

Description
Serum creatinine
Timepoint
Before ESWL, 14 days after ESWL
Method of measurement
Calorimetry

Intervention groups

1

Description
Intervention group: Boron supplement capsule containing 88.5 mg sodium tetraborate decahydrate (Sigma, St. Louis, USA), i.e. (containing 10 mg Boron), and 221.5 mg lactose powder (as a filling material) will prescribe in patients (more than 18 years of old) after ESWL, two times a day for two weeks.
Category
Treatment - Drugs

2

Description
In control group, patients more than 18 years of old will treated with cap. Tamsulosin, 0.4 mg, rvery night for two weeks after ESWL.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinejad clinic
Full name of responsible person
Maryam Taheri
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No 103, 9th Boustan St., Pasdaran Ave.
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The information about the type of treatment and the patients questionnaires will be available.
When the data will become available and for how long
The data could be available one year after the

publication of the results.

To whom data/document is available

Data will be available for academic faculty members and researchers.

Under which criteria data/document could be used

The control of the data and supplementary analyses of the data could be performed under copyright law.

From where data/document is obtainable

Urology and Nephrology Research Center: Dr. Maryam Taheri: taheri233@yahoo.com/ Ms. Shabnam Golshan: +98-21-22567222

What processes are involved for a request to access data/document

The applicant must submit a written request to the Urology and Nephrology Research Center. After the approval of the center and the PI of the proposal, the data will be available to the applicant.

Comments