

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

Country

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

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abbas Basiri

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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****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Taheri

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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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