Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the increasing effect of gabapentin supplementation on standard (anticholinergic) treatment in controlling stimulus symptoms after double J stent placement in ureteral stone patients

Protocol summary

Study aim
Evaluation of gabapentin supplementation on standard treatment in stimulus symptoms after double J stent in ureteral stone patients

Design
IRCT with control group, with parallel groups, one-way blind, randomized, phase 2 on 150 patients. it's method was Envelope.

Settings and conduct
Study will be performed in the urology department of Imam Reza Hospital. Ureteral stones Patients and TUL treatment with double J catheter, are studied. there are two groups of intervention by random allocation method. First one is treated with anticholinergics and gabapentin 100 and the second is treated with anticholinergics and placebo. 2 weeks later, the results of irritating symptoms are evaluated by using questionnaire (USSQ).

Participants/Inclusion and exclusion criteria
Patients with unilateral ureteral stones with more than 15 mm Having a double J catheter Over 18 years old Chronic use (more than 3 months) of alpha-blocker and analgesic drugs, history of neurogenic bladder, recurrent urinary tract infection or chronic pelvic pain, patient dissatisfaction, discontinuation during study, people who are contraindicated in gabapentin. High risk group due to drug drowsiness

Intervention groups
Intervention group: Administration of anticholinergic drugs and gabapentin 100 1 per day for ureteral stones patients whom double J stent has been used Control group: Prescribing anticholinergic and placebo drugs 1 per day for ureteral stones patients whom double J stent has been used

Main outcome variables
Stimulus symptoms are recorded and evaluated in all studied patients based on a questionnaire 2 weeks after the study.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170417033489N8**
Registration date: **2021-07-05, 1400/04/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-05, 1400/04/14**
Update count: **0**

Registration date
2021-07-05, 1400/04/14

Registrant information

Name
Salman Soltani

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 3802 2553

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soltanis@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the increasing effect of gabapentin supplementation on standard (anticholinergic) treatment in controlling stimulus symptoms after double J stent placement in ureteral stone patients

Public title
The effect of gabapentin supplementation in ureteral stone patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with unilateral ureteral stones more than 15 mm in diameter who have undergone TUL lithotripsy Patients should be over 18 years old A double G catheter is installed for them

Exclusion criteria:
Chronic use (more than 3 months) of alpha-blocker and analgesic drugs History of neurogenic bladder Recurrent urinary tract infections Chronic pelvic pain Patient dissatisfaction Leaving the study during the study process People who are contraindicated in gabapentin History of previous allergy to gabapentin Pregnancy Breastfeeding Liver failure Renal failure People who are in the high-risk group due to the drowsiness complication of the drug

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
After the visit of each patient with inclusion criteria, an envelope is taken in order and according to the code written in it (for example a / b) the patient is placed in one of two groups

Blinding (investigator's opinion)
Single blinded

Blinding description
After the visit of each patient with inclusion criteria, an envelope is taken in order and according to the code written in it (for example a / b) the patient is placed in one of two groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad Ethics Committee of the Medical School

Street address
Department of Knowledge & Health, Shahid Fakouri blvd, Mashhad, Khorasan Razavi

City
Mashhad

Province
Razavi Khorasan

Postal code
99191-91778

Approval date
2020-09-30, 1399/07/09

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.343

Health conditions studied

1

Description of health condition studied
ureteral stone disease

ICD-10 code
Z96.0

ICD-10 code description
Presence of urogenital implants

Primary outcomes

1

Description
Score obtained based on the patient's irritating symptoms questionnaire

Timepoint
Before intervention and 14 days after gabapentin

Method of measurement
ureteral stent symptom questionnaire (USSQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Treated with anticholinergics and gabapentin 100 mg orally once daily. Solifenacin 5 mg orally is used as an anticholinergic drug. After 2 weeks from the start of treatment, the results of improving the irritating symptoms are re-evaluated using the Persian

version of the ureteral stent symptom questionnaire (USSQ). In order to record other information such as patients' personal information, medical records and possible drug side effects during the study (dry mouth, hot flashes, temporary loss of balance, headache, drowsiness, body aches, etc.) from a simple design checklist Will be used by researchers.

Category

Prevention

2

Description

Control group: Second, they are treated with anticholinergics and placebo with the same prescription as the intervention group. and 5 mg oral sulfinacin is used as an anticholinergic drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Salman Soltani

Street address

Margin of Imam Reza Square, Ibn Sina Blvd, Mashhad.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Taffaghodi

Street address

Department of Knowledge and Health, Fakouri Blvd, Mahhad, Iran

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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

Dr.Salman Soltani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Salman Soltani

Position

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Latest degree

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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
Yes - There is 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
Title and more details about the data/document
Only part of the data, such as information about the main outcome, can be shared.
When the data will become available and for how long
Start of the access period three months after the publication of the results
To whom data/document is available
Academic and scientific institutions
Under which criteria data/document could be used
by sending an email
From where data/document is obtainable
by email soltanis@mums.ac.ir
What processes are involved for a request to access data/document
2 minths after recieving your request
Comments