Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating local effect of aminophylline on transureteral lithotripsy (TUL)

Protocol summary

Summary

The aim of this randomized double-blind clinical trial was to evaluate local effect of aminophylline on transureteral lithotripsy (TUL). A total of 120 patients, meeting eligibility criteria, were randomly allocated into the two equal groups. After establishing routine monitors and general anesthesia, the bladder was drained by catheter and then 150 cc Study irrigation solutions were entered the bladder through Ureteroscopy. Study irrigation solution in the control group was normal saline and in the intervention group was normal saline+ 250 mg aminophylline. After five minutes, bladder exposure to irrigation solution, ureteroscopy will be done. Duration the TUL, Success rate of stone removal, next need to ESWL, next need to use ureteral stents and DJ, tachycardia and hypertension during surgery, ureter evulsion during surgery, postoperative acute pyelonephritis associated with TUL will be measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106146803N1**
Registration date: **2011-07-22, 1390/04/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-22, 1390/04/31

Registrant information

Name

Abolfazl Firouzian

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2011-08-06, 1390/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating local effect of aminophylline on transureteral lithotripsy (TUL)

Public title

Lowering ureter spasm to increase success rate in ureteroscopy and to remove stone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: signing written Informed consent, ASA class I-II, Age between 15 and 45 years, Elective surgery, Lower ureteral stones smaller than 20 mm Exclusion criteria: history of renal colic, history of TUL, renal anatomical abnormalities, renal malfunction, use of NSAIDs, steroids and opioids, Hypersensitivity to theophylline or any component of the formulation

Age

From **15 years** old to **45 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran University of Medical Sciences
Street address
Mazandaran University of Medical Sciences, Moallem Square
City
Sari
Postal code
866-48175
Approval date
2011-01-18, 1389/10/28
Ethics committee reference number
89-96

Health conditions studied

1

Description of health condition studied
ureter stone
ICD-10 code
N20.1
ICD-10 code description
Calculus of ureter, Ureteric stone

Primary outcomes

1

Description
decreasing ureter espasm
Timepoint
once, during surgary
Method of measurement
increase succes rate in ureteroscopy and tul

Secondary outcomes

1

Description
time of TUL
Timepoint
once, during surgary
Method of measurement
Recorded in the questionnaire

2

Description
Rate of need for ESWL
Timepoint
once, during surgary
Method of measurement
Recorded in the questionnaire

3

Description
Rate of need for ureter stent
Timepoint
once, during surgary
Method of measurement
Recorded in the questionnaire

4

Description
Rate of need for ureter catheter
Timepoint
once, during surgary
Method of measurement
Recorded in the questionnaire

5

Description
Rate of the need for DJ
Timepoint
once, during surgary
Method of measurement
Recorded in the questionnaire

6

Description
Rate of ureter evulsion
Timepoint
once, during surgary
Method of measurement
Recorded in the questionnaire

7

Description

Rate of Acute pyelonephritis
Timepoint
after surgery
Method of measurement
Recorded in the questionnaire

8

Description
Success rate of stone removal
Timepoint
once, during surgary
Method of measurement
Recorded in the questionnaire

Intervention groups

1

Description
After draining the bladder by catheter, 150 cc Study irrigation solutions was entered the bladder through ureteroscopy. Study irrigation solution in the intervention group was normal saline+ 250 mg aminophylline. After five minutes, bladder exposure to irrigation solution ureteroscopy was done.
Category
Treatment - Surgery

2

Description
After draining the bladder by catheter, 150 cc Study irrigation solutions was entered the bladder through ureteroscopy. Study irrigation solution in the control group was normal saline. After five minutes, bladder exposure to irrigation solution ureteroscopy was done.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini General Hospital
Full name of responsible person
ayub barzegarnejad, MD, Urologist and renal transplant floship, Assistant professor
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Imam Khomeini general Hospital, Amir St.
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sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati, MD
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Mazandaran University of Medical Sciences, Moallem Square
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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
Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ayub Barzegarnejad, MD
Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty