Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of intravenous magnesium sulfate versus placebo on postoperative pain and urethral catheter discomforts in patients undergo transurethral ureterolithotripsy: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of intravenous magnesium sulfate versus placebo on postoperative pain and urethral catheter discomforts in patients undergo transurethral ureterolithotripsy Design: A double blinded randomized clinical trial. Setting and conduct: the eligible patients who are candidate for transurethral ureterolithotripsy and will refer to Shahid Beheshti Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a) candidate for transurethral ureterolithotripsy; (b) age of 18 to 70 years; (b) serum magnesium less than 2.5 mg/dl. Exclusion criteria: (a) transurethral ureterolithotripsy in combination with other procedure; (b) incomplete discharge of stone; (c) general anesthesia; (d) having renal disease. Intervention: Intravenous infusion of 25 mg/kg magnesium sulfate in 500 ml ringer serum 5 min before spinal anesthesia plus intravenous infusion of 25 mg/kg magnesium sulfate in 1000 ml ringer serum after surgery twice with an 8-hour interval. Control: Intravenous infusion of 500 ml normal saline 5 min before spinal anesthesia plus intravenous infusion of 500 ml normal saline after surgery twice with an 8-hour interval. Primary outcome: (a) severity of back pain using Numerical Rating Scale 6, 12, and 18 hours after surgery; (b) severity of flank pain using Numerical Rating Scale 6, 12, and 18 hours after surgery; (c) severity of abdominal pain using Numerical Rating Scale 6, 12, and 18 hours after surgery; (d) severity of urethral discomforts using Numerical Rating Scale 6, 12, and 18 hours after surgery. Secondary outcome: Number of analgesic used during 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410229014N45**

Registration date: **2014-10-28, 1393/08/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-28, 1393/08/06

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

1992-06-01, 1371/03/11

Expected recruitment end date

1993-06-01, 1372/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous magnesium sulfate versus placebo on postoperative pain and urethral catheter discomforts in patients undergo transurethral ureterolithotripsy: a double blinded randomized clinical trial

Public title
Effect of intravenous magnesium sulfate versus placebo on postoperative pain and urethral catheter discomforts in patients undergo transurethral ureterolithotripsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: (a) candidate for transurethral ureterolithotripsy; (b) age of 18 to 70 years; (b) serum magnesium less than 2.5 mg/dl. Exclusion criteria: (a) transurethral ureterolithotripsy in combination with other procedure; (b) incomplete discharge of stone; (c) general anesthesia; (d) having renal disease.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: The patients will be allocated to intervention and control groups through systematic randomization one at a time. Blinding: The patients in the intervention and control groups will receive serums with the same volume and color. Therefore, they will not aware of the intervention. In addition, the examiner will not aware of the type of intervention. Accordingly, the trial will be run as double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2014-07-18, 1393/04/27
Ethics committee reference number
D/P/16/35/9/3463

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
severity of back pain
Timepoint
6, 12, and 18 hours after surgery
Method of measurement
using Numerical Rating Scale

2

Description
severity of flank pain
Timepoint
6, 12, and 18 hours after surgery
Method of measurement
using Numerical Rating Scale

3

Description
severity of abdominal pain
Timepoint
6, 12, and 18 hours after surgery
Method of measurement
using Numerical Rating Scale

4

Description
severity of urethral discomforts
Timepoint
6, 12, and 18 hours after surgery
Method of measurement
using Numerical Rating Scale

Secondary outcomes

1

Description
Number of analgesic used
Timepoint
during 24 hours after surgery
Method of measurement
Medical record

Intervention groups

1

Description
Intravenous infusion of 25 mg/kg magnesium sulfate in 500 ml ringer serum 5 min before spinal anesthesia plus intravenous infusion of 25 mg/kg magnesium sulfate in 1000 ml ringer serum after surgery twice with an 8-hour interval.
Category
Treatment - Drugs

2

Description
Intravenous infusion of 500 ml normal saline 5 min before spinal anesthesia plus intravenous infusion of 500 ml normal saline after surgery twice with an 8-hour interval.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Zandra Golparvar
Street address
Shahid Beheshti Hospital, Eram Ave
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan 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
Name of organization / entity
Shahid Beheshti Hospital
Full name of responsible person
Zandra Golparvar
Position
Medical student
Other areas of specialty/work
Street address
Shahid Beheshti Hospital, Eram Ave.
City
Hamadan
Postal code
Phone
+98 81 3838 0705
Fax
Email
dr_golparvar_65@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti Hospital
Full name of responsible person
Dr Behrooz Karkhanei
Position
Anesthesiologist
Other areas of specialty/work
Street address
Shahid Beheshti Hospital, Eram Ave.
City
Hamadan
Postal code
Phone
+98 81 3838 0705

Fax
Email
Bk13472000@yahoo.com
Web page address

Person responsible for updating data

Contact

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