

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

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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

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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

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Person responsible for scientific inquiries

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Shahid Beheshti Hospital

Full name of responsible person

Dr Behrooz Karkhaneh

Position

Anesthesiologist

Other areas of specialty/work

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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