

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation the effect of pethidine and midazolam versus propofol and fentanyl on pain control during extracorporeal shock wave lithotripsy

Protocol summary

Summary

The Goal of this study is the evaluation of pethidine and midazolam versus propofol and fentanyl on pain control during extracorporeal shock wave lithotripsy. This single blind clinical trial will be done on 75 patients with renal stones who are candidates for extracorporeal shock wave lithotripsy in Imam Ali Hospital. Patients should be alert and have class 1 and class 2 American Society of Anesthesiologists scale (ASA) and no history of chronic use of analgesics or narcotics. Patients will be randomly allocated into two groups (using Random numbers table). First group will receive Intravenous Pethidine and midazolam (20 to 40 milligram pethidine and 1 to 2 milligram midazolam) and another group will receive Intravenous propofol and fentanyl (1.5 mg/ kg propofol and 1 Microgram / kg fentanyl) before beginning extracorporeal shock wave lithotripsy. The extracorporeal shock wave lithotripsy will be done according to standard methods in both groups. The level of pain experienced by patients will be evaluated at 15, 30, 45 and 60 minutes after finishing the procedure with visual analogue scale (VAS)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051427893N1**

Registration date: **2016-11-24, 1395/09/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-24, 1395/09/04

Registrant information

Name

Ramin Haghighi

Name of organization / entity

North Khorasan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Esfarayen University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of pethidine and midazolam versus propofol and fentanyl on pain control during extracorporeal shock wave lithotripsy

Public title

The effects of drugs on the pain after Lithotripsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Ability to read and write. Having consciousness in extent proper communication. No history of chronic use of narcotics and analgesics. No history of mental disorders. Age of 15-80 years old. Exclusion criteria: If the patient does not consent to be

excluded. If deeper anesthesia and using other drugs is necessary. Having allergy to propofol, pethidine, midazolam or fentanyl.

Age

From **15 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Random numbers table was used for the randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfarayen University of Medical Sciences

Street address

Medical Sciences Esfarayen, Taleghani Avenue, Esfarayen, North Korasan, Iran

City

Esfarayen

Postal code

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

IR.ESFARAYENUMS.REC

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 pain

Timepoint

In the times of 15, 30, 45 and 60 minutes after Intervention

Method of measurement

Visual Pain Scale (VAS)

Secondary outcomes

1

Description

Satisfaction

Timepoint

After a full consciousness of the patient

Method of measurement

Using the checklist and self-report scale

Intervention groups

1

Description

First group will receive Intravenous Pethidine and midazolam (20 to 40 milligram pethidine and 1 to 2 milligram midazolam) before beginning extracorporeal shock wave lithotripsy.

Category

Treatment - Drugs

2

Description

another group will receive Intravenous propofol and fentanyl (1.5 mg/ kg propofol and 1 Microgram / kg fentanyl) before beginning extracorporeal shock wave lithotripsy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Haghighi Ramin Fellowship in Endourology and Urolaparoscopy

Street address

Imam Ali Hospital, Shahriar Ave, Bojnourd, Iran

City

Bojnourd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Esfarayen University of Medical Sciences

Full name of responsible person

Shoja Mohsen

Street address

Medical Sciences Esfarayen, Taleghani Avenue, Esfarayen, North Korasan, Iran

City

Esfarayen

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 of Esfarayen 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

North Khorasan University of Medical Sciences

Full name of responsible person

Ahmad Kameli

Position

Instructor

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Web page address

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