# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 on75 patients with renal stones who are candidates for extracorporeal shock wave lithotripsy in Imam Ali Hospital. Patients should be alert and have class1 and class2 America 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)

**Phone**

+98 58 3272 4475

**Email address**

haghighi.ramin@yahoo.com

**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
**Other areas of specialty/work**
**Street address**
School of Nursing, Shahriar Ave, Bojnourd, Iran
**City**
Bojnourd
**Postal code**
**Phone**
+98 58 3229 6909
**Fax**
**Email**
ahmad_kamely@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
North Khorasan University of Medical Sciences
**Full name of responsible person**
Ahmad Kameli
**Position**
Instructor
**Other areas of specialty/work**
**Street address**
School of Nursing, Shahriar Ave, Bojnourd, Iran
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**Postal code**
**Phone**
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
North Khorasan University of Medical Sciences
**Full name of responsible person**
Ahmad Kameli
**Position**
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**Street address**
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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*