

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of efficacy and complications of Fentanyl and combination of Midazolam and Pethedine for pain control in ESWL

Protocol summary

Summary

The aim of this study was to compare the efficacy and complications of Fentanyl and combination of Midazolam and Pethedine for pain control in ESWL. One hundred Patients, older than 18 years old with renal or upper ureteral stones with size between 6-25 millimeter who were candidate for extracorporeal shockwave lithotripsy (ESWL), were randomly allocated into one of two study groups to receive 50 milligrams of Pethedine as well as 1 milligram of Midazolam or only 50 micrograms of Fentanyl. The medications were injected intravenously 5 minutes before ESWL. In both groups, procedures were done in supine position under fluoroscopic guidance by standard technique until intolerance of patients or giving maximum shock of 4000. During the procedure, oxygen saturation was checked by pulse oximetry. Blood pressure and severity of pain through visual analogue scale were checked every 20 minutes until two hours. After ESWL, the patients were followed up for two hours and the patients' satisfaction was checked by seven point verbal scale. Two weeks later, sonography was done to see if ESWL had worked and also if any adverse effect had happened during that time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711051323N2**

Registration date: **2010-05-29, 1389/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-29, 1389/03/08

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research vice chancellor Yasuj University of Medical Sciences

Expected recruitment start date

2008-08-20, 1387/05/30

Expected recruitment end date

2010-04-29, 1389/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and complications of Fentanyl and combination of Midazolam and Pethedine for pain control in ESWL

Public title

Comparison of efficacy and complications of Fentanyl and combination of Midazolam and Pethedine for pain control in ESWL

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 18 years, renal or upper ureteral stone, stone size between 6-25 mm Exclusion criteria: Presence of Coagulopathy, presence of

neuropathy, stone size more than 25mm in kidney and more than 15mm in ureter, presence of active infection, presence of azotemia, uncontrolled hypertension, hypersensitivity to narcotic drugs, pregnancy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Yasuj University of Medical Sciences

Street address

Yasuj university of Medical Sciences, Motahari street,
Yasuj, Iran

City

Yasuj

Postal code

7591741417

Approval date

empty

Ethics committee reference number

2620/5/23/پ

Health conditions studied

1

Description of health condition studied

Calculus of kidney and ureter

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

pain

Timepoint

Before procedure and every 20 minutes during operation and one hour later

Method of measurement

Visual analoge scale

Secondary outcomes

1

Description

clerance of kidney or ureter from the stone

Timepoint

2 weeks later

Method of measurement

ultrasonography and KUB

2

Description

Pulmonary or cardiovascular complications

Timepoint

Before procedure and every 20 minutes during the operation and one hour later

Method of measurement

Checking blood pressure every 20 minutes and Pulseoximety during the procedure

Intervention groups

1

Description

intravenous injection of 50 mligrams Pethedin and 1 miligram Midazolam, 5 minutes before ESWL

Category

Treatment - Drugs

2

Description

intravenous injection of 50 microgram of Fentanyl 5 minutes before ESWL

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Beheshti Hospital

Full name of responsible person

Dr Sadrollah Mehrabi

Street address

Shaheed Behesti Hospital Shaheed Montazeri Street
City
Yasuj

Email
mehrabi390@yahoo.com and dr mehrabiyums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research manager of Yasuj University of Medical Sciences
Full name of responsible person
Dr Mehdi Akbartabar
Street address
Emam Sajad Hospital, Research Vice chancelor of Yasuj University of Medical Sciences
City
Yasuj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research manager of Yasuj 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
Urology Department, Yasuj University of Medical Sciences
Full name of responsible person
Dr Sadrollah Mehrabi
Position
Associate profesoor, Fellowship of endourology and urolaparoscopy
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Person responsible for scientific inquiries

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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