Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 oximetery. 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

Pulmunary 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 Pulseoximetey 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 Behehti Hospital

Full name of responsible person

Dr Sadrollah Mehrabi

Street address

Shaheed Behesti Hospital Shaheed Montazeri Street

City

Yasuj

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 Hospial, 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, Felloship of endourology and urolaparoscopy

Other areas of specialty/work

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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