

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of Effect of intravenous injection of pethidine plus piroxicam or lidocaine gel topical in reducing pain during the ESWL and comparison with intravenous injection of pethidine alone

Protocol summary

Summary

An external organ crusher noninvasive method to break stones using the administrative apparatus Shock waves are acoustic waves, but these effects cause temporary pain and discomfort in the deep waves of entry is visceral. Housing that require administration over the action necessary to make this study on 159 patients to the hospital for surgery ESWL Ayatollah Kashani was referred 53 patients to three-person groups were assigned randomly: the first group, intravenous pethidine mg 25 alone, the second group, intravenous pethidine mg 25 plus topical piroxicam gel, and the third group mg 25 gel lidocaine with intravenous pethidine Flank position in the area for half an hour before surgery patients were used. During the operation each patient had unbearable pain again mg 25 pethidine was injected intravenously. Postoperative Pain Questionnaire based MC Gill was measured. Results showed that all three groups with different age and sex were not significant and significant difference in pain scores in three groups of patients there was a ($P < 0.01$) measure of average pain in the first group (pethidine) 6.2 ± 6.9 and the second group (pethidine piroxicam gel) 2.7 ± 2.3 and the third group (pethidine lidocaine gel) 3.1 ± 3.9 was. Mean difference in pain pethidine group and the other groups was significant. ($P < 0.05$) Average amount of drug use in the first group pethidine (pethidine alone) 24 ± 16 mg, the second group (pethidine+ piroxicam gel) 5 ± 9 mg and the third group (pethidine +lidocaine gel) 10 ± 13 mg. Average differences in drug taking pethidine with two other groups had significant differences ($P < 0.05$). This study showed that piroxicam gel or lidocaine reduces pain in patients after ESWL, and the need for drug consumption reduces.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811043156N1**

Registration date: **2010-12-29, 1389/10/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-29, 1389/10/08

Registrant information

Name

Mohammad Moazeni Bistgani

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 4445

Email address

drmoazeni@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

shahrekord university of medical sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2009-09-23, 1388/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Effect of intravenous injection of pethidine plus piroxicam or lidocaine gel topical in reducing pain during the ESWL and comparison with intravenous injection of pethidine alone

Public title

Study of Effect of topical piroxicam or lidocaine in reducing pain during the ESWL and compared with intravenous injection of pethidine alone

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion : want to participate in the plan- absence severe hydronephrosis Exclusion: Presence severe hydronephrosis

Age

No age limit

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 159

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

shahrekord university of medical sciences

Street address

aiatollah kashahni street

City

shahrekord

Postal code

Approval date

2009-02-21, 1387/12/03

Ethics committee reference number

9-12-87

Health conditions studied

1

Description of health condition studied

Pain during ESWL

ICD-10 code

N 20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

pain

Timepoint

immediatly after ESWL

Method of measurement

McGill Questionnaire during ESWL procedure

Secondary outcomes

empty

Intervention groups

1

Description

petidin (IV) 25 mg + lidokaein gel

Category

Other

2

Description

petidin (IV)25 mg + piroxicam gel

Category

Other

3

Description

petidin (IV) 25 mg

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

aiatollah kashani educational therapy center

Full name of responsible person

aiatollah kashani educational therapy center

Street address

City

shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

shahrekord university of medical sciences

Full name of responsible person

dr. mobasheri mahmood

Street address

research assistant

City

shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

shahrekord 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

shahrekord university of medical sciences

Full name of responsible person

dr.moazeni bistgani mohammad

Position

thoracic surgeon

Other areas of specialty/work

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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