

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The comparative effects of paracetamol and fentanyl on pain control during extracorporeal shockwave lithotripsy

Protocol summary

Summary

The aims of this study is to compare 1.The efficacy of paracetamol for pain control during ESWL(extracorporeal shock wave lithotripsy).2.The efficacy of fentanyl for pain control during ESWL .3.The side effects of paracetamol for pain control during ESWL. 4.compare the efficacy and side effects of paracetamol and fentanyl for pain control duringThe side effects of fentanyl for pain control during ESWL. In this randomized single blind study, 105 patients with upper urinary tract stones undergoing SWL were randomly divided into two groups. Group P received 15mg/kg of paracetamol 10 min before procedure, and group F (n = 30) received 1 µg/kg intravenous fentanyl 3 min before procedure. Pain scores assessed with the 10-score linear visual analogue pain scale (VAS).When patients VAS value was over four, supplemental analgesia was administered to both of the groups. VAS scores, systolic and diastolic blood pressure, and peripheral oxygen saturation were recorded before procedure and every 10 minutes during the ESWL. Side effects (nausea, vomiting) and the satisfaction score were recorded.Inclusion Criteria were: patients between 20 to 65 years of age, and having upper ureteric stones6-20mm. Exclusion criteria included: allergy study drugs, moderate to severe hydronephrosis, presence of multiple and/or bladder and/or radiolucent stones, pregnancy, sensory neurological disease. Patients and Methods: In this randomized single blind study, 102 patients with upper urinary tract stones undergoing SWL were randomly divide into two groups. Group A receive 15mg/kg of paracetamol 10 min before procedure, and group F (n = 30) receive 1 µg/kg intravenous fentanyl 3 min before procedure. Pain scores assesse with the 10-score linear visual analogue pain scale (VAS).When patients VAS value is over four, supplemental analgesia administer to both of the groups. VAS scores, systolic and diastolic blood pressure, and peripheral oxygen saturation record before procedure and every 10 minutes during the ESWL. Side effects

(nausea, vomiting) and the satisfaction score will record.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072329034N1**

Registration date: **2016-09-01, 1395/06/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-01, 1395/06/11

Registrant information

Name

Ashkan Abdinezhad

Name of organization / entity

Iran University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Science

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative effects of paracetamol and fentanyl on pain control during extracorporeal shockwave lithotripsy

Public title

Effects of paracetamol and fentanyl on pain control during extracorporeal shockwave lithotripsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria : patients between 20 to 65 years of age; Patients with American Society of Anesthesiologists (ASA) physical status I or II ; patients having upper ureteric stones 6-20mm. Exclusion criteria included: a history of chronic use of analgesics or alcohol; use any analgesic drug within 3 days before the procedure; allergy study drugs; under treatment of sedative or anti-depressant drugs; signs and symptoms of urinary tract infection; allergy to study drugs; moderate to severe hydronephrosis; presence of multiple and/or bladder and/or radiolucent stones; pregnancy; sensory neurological disease.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran University of Medical Science

Street address

Iran University of Medical Science, Hemmat freeway, next to Milad tower Tehran,

City

Tehran

Postal code**Approval date**

2015-03-16, 1393/12/25

Ethics committee reference number

93/6240 /105/3

Health conditions studied**1****Description of health condition studied**

Calculus of kidney

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

2**Description of health condition studied**

Opioids and related analgesics

ICD-10 code

Y45.0

ICD-10 code description

Opioids and related analgesics

Primary outcomes**1****Description**

Pain score

Timepoint

every 10 min until the end of shock wave lithotripsy

Method of measurement

visual analogue scale (VAS)

Secondary outcomes**1****Description**

Nausea and Vomiting

Timepoint

after ESWL procedure

Method of measurement

Side effects ranged 1 to 3: one related to no nausea, two related to nausea without vomiting and nausea with vomiting is shown with score three

Intervention groups**1****Description**

group F receive 1 µg/kg intravenous fentanyl three minutes before ESWL (Extracorporeal shock wave lithotripsy). When visual analogue pain scale is over 3, supplemental analgesia administered to the group. Intravenous fentanyl 25 micrograms should be given in

this condition.

Category

Treatment - Drugs

2

Description

Group A receive 15 mg/kg intravenous paracetamol ten min before ESWL (Extracorporeal shock wave lithotripsy).When visual analogue pain scale is over 3, supplemental analgesia administere to the group. Intravenous fentanyl 25 micrograms should be given in this condition.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashemi Nejad Kidney Center

Full name of responsible person

Ashkan Abdinezhad

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Mrs Kordlu

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Iran University of Medical Science, Hemmat freeway, next to Milad tower Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Science

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

Abdinezhad

Full name of responsible person

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Position

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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