Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 hydroureteronephrosis, 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

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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 stones6-20mm. 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 hydroureteronephrosis; 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/د

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 1to 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 administere 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

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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

Ashkan

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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