

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Name

Ashkan Abdinezhad

##### Name of organization / entity

Iran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8826 3826

##### Email address

dr.abdinezhad@gmail.com

##### 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 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 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

**Street address**

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**

Ashkan

**Position**

Resident of anesthesiology

**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*