Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of oral diclofenac sodium versus acetaminophen codeine on pain during Extracorporeal Shock Wave Lithotripsy (ESWL).

Protocol summary

Summary

The aim of this single blind randomized clinical trial is to campare analgesic effect of acetaminofen codein versus diclofenac sudiom on pain during Extracorporeal Shock Wave Lithotripsy in patients who refer to lithotripsy ward of Shaheed Beheshti hospital. After signing informed consent, 90 the eligible patients will be assigned randomly three different groups. The acetaminofen codein (A), diclofenac sudiom (B) and no drug (C). The A group will receive orally 650mg acetaminophen with 20mg codein and B group will receive 50mg diclofenac sudiom one hour before procedure and C group will receive no drug. Severity of pain assists with Four Point Scale (FPS) before administration of drugs and during procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081711822N6**
Registration date: **2015-09-05, 1394/06/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-05, 1394/06/14

Registrant information

Name

Behrooz Karkhanei

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0574

Email address

karkhanei@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan Univesity of Medical Sciences

Expected recruitment start date

2015-08-16, 1394/05/25

Expected recruitment end date

2015-08-26, 1394/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral diclofenac sodium versus acetaminophen codeine on pain during Extracorporeal Shock Wave Lithotripsy (ESWL).

Public title

Analgesic effect of Diclofenac and Acetaminophen in lithotripsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclucion criteria: 18<age<70; ASA<II Exclusion criteria: History of peptic ulser; G6PD Deficiency; Liver or kidney disease; analgesic agent use 24 hr before lithotripsy; Drug sensitivity; addiction

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
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
Hamedan University of Medical Sciences

Street address
SHaheed Fahmideh str. Hamedan University of Medical Sciences

City
Hamedan

Postal code

Approval date
2015-08-17, 1394/05/26

Ethics committee reference number
IR.UMSHA.REC.1394 270

Health conditions studied

1

Description of health condition studied
calculus of kidney

ICD-10 code
n20.0

ICD-10 code description
calculus of kidney

Primary outcomes

1

Description
pain

Timepoint
at the time of ESWL and after

Method of measurement
four point scale

Secondary outcomes

1

Description
morphin dose

Timepoint
at the end of ESWl

Method of measurement
dosage

Intervention groups

1

Description
Diclophenac sodium- tablet 50mg-one hour before ESWL

Category
Treatment - Drugs

2

Description
Acetaminophen codein- tablet-300/10mg. no=2, one hour befor ESWL

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Mehta Razzaghi

Street address

City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Behroz Karkhanei

Street address
Shahid Beheshti Hospital of Hamedan

City
Hamedan

Grant name

Grant code / Reference number

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

Title of funding source
Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mehta Razzaghi

Position

Medical Student

Other areas of specialty/work

Street address

Shahid Beheshti Hospital of Hamedan

City

Hamedan

Postal code

6516953339

Phone

+98 87 3824 6647

Fax

Email

Mehta_razzaghi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Behroz karkhanei

Position

Assistant Professor

Other areas of specialty/work

Street address

Hamedan- Shahid Beheshti Hospital

City

Hamedan

Postal code

Phone

+98 81 3838 0704

Fax

Email

Bk13472000@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Farshid Mohammadi

Position

Medical Doctor

Other areas of specialty/work

Street address

Hamedan. Saeidieh str.

City

Hamedan

Postal code

6516953339

Phone

+98 81 3824 6647

Fax

Email

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