

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 compare analgesic effect of acetaminophen codeine versus diclofenac sodium 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 acetaminophen codeine (A), diclofenac sodium (B) and no drug (C). The A group will receive orally 650mg acetaminophen with 20mg codeine and B group will receive 50mg diclofenac sodium one hour before procedure and C group will receive no drug. Severity of pain assessed 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 University 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

Inclusion criteria: 18<age<70; ASA<II Exclusion criteria: History of peptic ulcer; 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 before 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

Hamedan
Postal code
Phone
+98 81 3838 0704
Fax
Email
Bk13472000@yahoo.com
Web page address

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

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