

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The efficacy of Papaverine Hydrochloride with Diclofenac Na in the treatment of acute renal colic

Protocol summary

Vice-chancellor for Research, Guilan University of Medical Sciences

Summary

This study is a double blind randomized clinical trial to survey the efficacy of papaverine in the treatment of acute renal colic. 550 patients with renal colic visited in Rasht Razi Urology Clinic were randomly assigned with block randomization method to receive suppository Diclofenac 100mg or suppository Diclofenac 100mg + papaverine 120mg combined with N/S 0.9% infused intravenously, in 3 minutes. Renal colic pain was compared between groups.

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2010-05-21, 1389/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808251853N4**

Registration date: **2009-11-16, 1388/08/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-11-16, 1388/08/25

Registrant information

Name

Siavash Falahatkar

Name of organization / entity

Urology Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 3352 5259

Email address

urc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Scientific title

The efficacy of Papaverine Hydrochloride with Diclofenac Na in the treatment of acute renal colic

Public title

The efficacy of Papaverine Hydrochloride with Diclofenac Na in the treatment of acute renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 15-55 years, symptoms of renal colic with any of the followings: hematuria detected by urine analysis, calculi detected by Genitourinary radiography or by sonography. Exclusion criteria: complete AV block, coronary artery disease, bronchial asthma, peptic ulcer disease, coagulopathy, anticoagulant therapy, sensitivity to Diclofenac or papaverin, renal or liver insufficiency, pregnancy, breast feeding, receiving any analgesics in the past 4 hours.

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 550

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Science

Street address

Guilan University of Medical Sciences

City

Rasht

Postal code

41448-95655

Approval date

2009-07-14, 1388/04/23

Ethics committee reference number

3092

Health conditions studied

1

Description of health condition studied

Renal colic

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

Primary outcomes

1

Description

renal colic pain

Timepoint

10 month

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Diclofenac Na, 100 mg, suppository plus papaverin 120 mg intravenous

Category

Treatment - Drugs

2

Description

Diclofenac Na, 100 mg, suppository

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr Seyyed Alaeddin Asgari

Street address

Razi Hospital, Sardar Jangal street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Guilan University of Medical Sciences

Full name of responsible person

Dr Abdolrasoul Sobhani- Research Assistant of Guilan University of Medical Sciences

Street address

Guilan University of Medical Sciences

City

Rasht

Grant name

معاونت پژوهشی دانشگاه علوم پزشکی و خدمات بهداشتی- درمانی گیلان

Grant code / Reference number

10506

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

Yes

Title of funding source

Vice-chancellor for Research, Guilan 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

Urology Research Center

Full name of responsible person

Dr Mani Mohiti Asl

Position

Co worker/Resident

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Seyyed Alaeddin Asgari

Position

Associate Professor of Guilan University of Medical Sciences

Other areas of specialty/work

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Contact

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Urology Research Center

Full name of responsible person

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Secretor of Urology Research Center/Bachelor

Other areas of specialty/work

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www.urc.ir

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