

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of analgesic effects of Morphine and Indomethacin suppositories in patients with clinical diagnosis of renal colic referred to emergency wards of Shariati and Imam Khomeini hospitals

Protocol summary

Summary

(1) Objectives: Comparison of analgesic effects of Morphine and Indomethacin suppositories in patients with clinical diagnosis of renal colic referred to emergency wards of Shariati and Imam Khomeini hospitals; (2) Design: The study is a randomized, multicenter, double-blinded clinical trial which is conducted on adult patients; (3) Setting and methods: Patients with clinical diagnosis of renal colic referred to Shariati and Imam Khomeini hospitals are randomly divided into two groups. One of the groups is treated with 100 mg indomethacin suppository and the other group with 10 mg morphine suppository; (4) Participants including major eligibility criteria: The main inclusion criteria: Patients between 18-85 years old referred to emergency ward with clinical diagnosis of renal colic initially diagnosed by triage nurses and confirmed by emergency medicine residents; The main Exclusion criteria: Substance abuse; Taking analgesics 4 hours before referral; Past history of drug reaction to morphine or NSAIDs; Refuse to take rectal analgesic drug; (5) Interventions: One of the intervention groups is treated with 100 mg indomethacin suppository and other group with 10 mg morphine suppository; (6) Main outcome measures: Pain severity is assessed at the emergency entrance and after 20, 40, 60 and 90 minutes using Visual Analogue Scale (VAS). Concomitant symptoms, any drug side effects (nausea and vomiting, drowsiness, allergy) or any changes in vital signs are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050514297N2**
Registration date: **2014-06-01, 1393/03/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-01, 1393/03/11

Registrant information

Name

Seyed Mojtaba Aghili

Name of organization / entity

Imam Khomeini Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6690 4848

Email address

m-aghili@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effects of Morphine and Indomethacin suppositories in patients with clinical diagnosis of renal colic referred to emergency wards of Shariati and Imam Khomeini hospitals

Public title

Comparison of analgesic effects of Morphine and Indomethacin suppositories in patients with clinical diagnosis of renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 18-85 years old with clinical diagnosis of renal colic referred to emergency ward; Consent to participate in the trial Exclusion criteria: Patient's refusal for entering the study; Pregnancy; Substance abuse; Taking analgesics 4 hours before referral; Past history of drug reaction to morphine or NSAIDs; Refuse to take rectal analgesic drug; Diarrhea; Past history of chronic liver or kidney disease, COPD, Hypercapnea, Mild or severasthma, Sleep apnea syndorme, History of ileus, paralytic, Hypotension, IBD, Chronic Pancreatitis, Chronic bile duct dysfunction, Confusion, Severe anemia,Hipnotic drugs and phenothiazine, Adrenocortical dysfunction, Untreated hypothyroidism, Hypovolemia; Breast feeding; Chronic consumption of NSAIDs; Peritonitis

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **158**

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**

Ethics Committee of Tehran University of Medical Sciences

Street address

Sixth Floor, Central Organization for University, Ghods St., Keshavarz's Blvd

City

Tehran

Postal code**Approval date**

2014-03-12, 1392/12/21

Ethics committee reference number

2995/130/92/3

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**

The analgesic effect of drugs

Timepoint

Immediately before, 20, 40, 60 and 90 minutes after drugs administration

Method of measurement

Pain scores (VAS)

Secondary outcomes**1****Description**

Vital sign changes

Timepoint

Immediately before, 20, 40 and 60 minutes after administration of drugs

Method of measurement

Clinical examination

2**Description**

Nausea and vomiting

Timepoint

Immediately before, 20, 40 and 60 minutes after administration of drugs

Method of measurement

Questionnaire

3**Description**

Drowsiness

Timepoint

Immediately before, 20, 40 and 60 minutes after administration of drugs

Method of measurement

Questionnaire

4

Description

Dry mouth

Timepoint

Immediately before, 20, 40 and 60 minutes after administration of drugs

Method of measurement

Questionnaire

5

Description

Allergy

Timepoint

Immediately before, 20, 40 and 60 minutes after administration of drugs

Method of measurement

Clinical examination and Questionnaire

Intervention groups

1

Description

In the first intervention group, 100 mg Indomethacin suppository (the standard treatment for renal colic) is administered.

Category

Treatment - Drugs

2

Description

In the other group 10 mg morphine suppository is administered

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Dr Shariati and Imam Khomeini Hospitals

Full name of responsible person

Seyed Mojtaba Aghili

Street address**City**

Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masoud Younesian

Street address

Sixth Floor, Central Organization for University, Ghods St., Keshavarz's Blvd.

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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

Vice chancellor for research, Tehran 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**

Imam Khomeini Hospital

Full name of responsible person

Forough Zamanian

Position

Emergency Medicine Assistant

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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Seyed Mojtaba Aghili

Position

Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity
Imam Khomeini Hospital
Full name of responsible person
Forough Zamanian
Position
Emergency Medicine Assistant
Other areas of specialty/work
Street address
Imam Khomeini Hospital, Keshavarz Blvd
City
Tehran
Postal code

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