

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of analgesic effect of paracetamol and morphine VS morphine in abdominal pain with suspected biliary origin in the Emergency Department of Shariati and Imam Khomeini Hospitals

Protocol summary

Summary

(1) Objectives: Comparison of the analgesic effect of paracetamol and morphine combination with morphine alone, in patients with abdominal pain with a biliary origin who referred to the Emergency Department. (2) Design: The study was a randomized, multicenter, double-blind, parallel group clinical trial that studied adult patients. (3) Setting and conduct: Patients presenting to the emergency department with abdominal pain were examined by emergency medicine residents at the initial exam room and if abdominal pain of biliary origin is suspected for patients (biliary colic, cholecystitis or cholangitis) are referred to enroll in the study. Patients divided into two groups with using the block randomization. The study is fully explained to the patients and, if patients desired, after obtaining written consent, are included to study. (4) The main inclusion criteria: Age ≥ 18 and ≤ 65 years; pain score of NRS ≥ 3 and main exclusion criteria: Known hypersensitivity to opioids or paracetamol; Pregnancy; Transplant patients; Patients with known renal, liver and heart failure; Taking analgesic over the past 6 hours or Methadone consumption. (5) Intervention: To the intervention group we infuse Morphine 0.05 mg/kg and 1000 mg Paracetamol in 100 cc of Normal Saline solution within 15 minutes. To the control group we infuse Morphine 0.1 mg/kg and 100 cc of Normal Saline solution as a placebo within 15 minutes. After 30 minutes if the patient is still in pain and difference his pain of his first VAS score and post analgesic score less than 13mm or when patients request pain medication for relief (Within 60 minutes of being under observation) the rescue doses (fentanyl, 0.75 μg / kg intravenous) is infused. (6) Main outcome measures: Vital signs and pain intensity measured based on VAS and NRS pain scores (immediately before and 15 and 30 minutes after administration of the drugs). Side effects of prescribed drugs or the need for rescue doses

of Fentanyl (Within 60 minutes of being under observation) is being recorded in the questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206099984N1**

Registration date: **2012-10-08, 1391/07/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-08, 1391/07/17

Registrant information

Name

Rasoul Babaei

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6687 7214

Email address

r-babaei@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of analgesic effect of paracetamol and morphine VS morphine in abdominal pain with suspected biliary origin in the Emergency Department of Shariati and Imam Khomeini Hospitals

Public title
Comparison of the analgesic effect of paracetamol and morphine with morphine alone in patients with abdominal pain suspected biliary origin

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Aged ≥ 18 and ≤ 65 years; Abdominal pain that clinical or Para clinical (evidence of gallbladder or biliary tract stones during the last 12 months) is in favor of biliary origin; NRS ≥ 3 . Exclusion criteria: Aged < 18 years and > 65 years; Known hypersensitivity to opioids or paracetamol; Unstable vital signs: systolic blood pressure < 90 mmHg; Evidence of peritoneal irritation; Pregnancy; Prior to entering the study; Patients with known renal, hepatic or cardiac failure; Patients with transplants (kidney, lung, liver, or heart); Lack of patient consent for participation in the study; Decreased level of consciousness (GCS < 15); Mental retardation; NRS < 3 ; having received Analgesics during the last 6 hours before presenting to the emergency department; Addiction to opium or methadone use.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
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

2012-07-22, 1391/05/01

Ethics committee reference number

828/130/91/5

Health conditions studied

1

Description of health condition studied

Abdominal pains with biliary origin

ICD-10 code

R10.1

ICD-10 code description

Pain localized to upper abdomen

Primary outcomes

1

Description

The analgesic effect of drugs

Timepoint

Immediately before, 15, 30 minutes after drugs administration

Method of measurement

Pain scores (VAS, NRS)

Secondary outcomes

1

Description

Requirement to rescue doses of fentanyl

Timepoint

No significant reduction in pain 30 minutes after drug administration (difference between first and last VAS < 3 mm) and ask for pain medication by the patient at any time during the one hour under the observation

Method of measurement

Clinical examination and asking the patient

2

Description

Pruritus, Rash

Timepoint

Within one hour after administration of drugs

Method of measurement

Clinical examination and questionnaire

3

Description

Dizziness

Timepoint

Within one hour after administration of drugs

Method of measurement

Clinical examination and questionnaire

4

Description

Nausea and vomiting

Timepoint

Within one hour after administration of drugs

Method of measurement

Clinical examination and questionnaire

5

Description

Hypotension

Timepoint

Within one hour after administration of drugs

Method of measurement

Clinical examination and questionnaire

Intervention groups

1

Description

For the intervention group we infused 1000mg paracetamol in 100 cc normal saline over 15 min and 0.05mg/kg morphine that diluted in 5cc normal saline over 5 mins.

Category

Treatment - Drugs

2

Description

In the control group we infused 0.1mg/kg morphine diluted into 5 ml normal saline within 5 mins.

Category

Treatment - Drugs

3

Description

In the control group we infused 100 cc normal saline within 15 mins.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Shariati Hospital

Full name of responsible person

Farnia Mohammad Reza

Street address

Dr Shariati Hospital, Jalal al e Ahmad Junction, North Karegar st.

City

Tehran

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Farnia Mohammad Reza

Street address

Imam Khomeini Hospital, End of Keshavarz Blvd.

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

Fotouhi Akbar

Street address

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

City

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

Shariati Hospital

Full name of responsible person

Babaei Rasoul

Position

Emergency Medicine Resident

Other areas of specialty/work**Street address**

Shariati hospital, Jalal al e Ahmad Junction, North karegar st.

City

Tehran

Postal code**Phone**

+98 21 8490 2719

Fax

+98 21 8863 3039

Email

r-babaei@razi.tums.ac.ir; rasoul.babaei@gmail.com

Web page address

dr.farniamohamad@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Dr Shariati Hospital

Full name of responsible person

Babaei Rasoul

Position

Emergency Medicine Resident

Other areas of specialty/work**Street address**

Shariati Hospital, Jalal al e Ahmad Junction, North Karegar st.

City

Tehran

Postal code**Phone**

+98 21 8490 2719

Fax**Email**

r-babaei@razi.tums.ac.ir; rasoul.babaei@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Dr Shariati Hospital

Full name of responsible person

Farnia Mohammad Reza

Position

Assistant

Other areas of specialty/work**Street address**

Dr Shariati Hospital, Jalal al e Ahmad Junction, North Karegar st.

City

Tehran

Postal code**Phone**

+98 21 8490 2719

Fax**Email****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