Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 ˃65years; Known hypersensitivity to opioids or paracetamol; Unstable vital signs: systolic blood pressure ˂90mmHg; 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/د

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 salin over 15 min and 0.05mg/kg morphine that diluted in 5cc normal salin 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

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
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

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