Clinical Trial Protocol
Iranian Registry of Clinical Trials
07 Jul 2019

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.

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
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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
None

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

Country
Iran (Islamic Republic of)

Postal code

Approval date
2012-07-22, 1391/05/01

Ethics committee reference number
828/130/91/

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

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

Country
Iran (Islamic Republic of)

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
empty

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

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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Farnia Mohammad Reza
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Assistant
Other areas of specialty/work
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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