Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the analgesic effect of intravenous acetaminophen and fentanyl in thoracic and abdominal surgery of neonates

Protocol summary

Study aim
Replacement of intravenous acetaminophen for fentanyl to control pain after thoracic and abdominal surgeries in neonates

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
This randomized controlled study will be done in neonatal intensive cares unit of Urmia Shahid Motahary and Shiraz Namazi hospitals on 66 neonates.Then neontes will be divided to 2 groups, randomly. One group will receive acetaminophen and the other group will receive fentanyl . If in each group pain scale is more than 7 they receive one dose of fentanyl which is reliefing dose. the relief dose. If relief doses in both groups gone out of 3 doses, that case would be excluded from the study.

Participants/Inclusion and exclusion criteria
Inclusion: Neonates with gestational age of 36 weeks and more with thoracic or abdominal surgery Exclusion: Neonates with allergy to morphine, fentanyl or acetaminophen or hepatic or renal dysfunction

Intervention groups
Neontes will be divided to 2 groups, randomly. One group will recieve fentanyl , and the other group will recieve acetaminophen .

Main outcome variables
The main variable in our study is effective pain control after abdominal or thoracic surgeries in neonates.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171218037936N2**
Registration date: **2019-03-11, 1397/12/20**
Registration timing: **prospective**
Last update: **2019-03-11, 1397/12/20**
Update count: **0**

Registration date
2019-03-11, 1397/12/20

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2019-06-21, 1398/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the analgesic effect of intravenous acetaminophen and fentanyl in thoracic and abdominal surgery of neonates

Public title
Comparison of the analgesic effect of intravenous acetaminophen and fentanyl (opiate analgesic) in thoracic and abdominal surgery of neonates

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Neonates with gestational age of 36 weeks and more with thoracic surgery Neonates with gestational age of 36 weeks and more with abdominal surgery

Exclusion criteria:

Allergy history to morphine, fentanyl or acetaminophen Hepatic dysfunction Renal dysfunction

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use blocked randomization method in order to allocate cases to two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Only the researcher knows double blindness, who is different from clinical care giver. As the study cases are neonates, and evaluation is based on behavior and vital signs, there will be no need to blind the study cases.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Research deputy of Urmia university of medical sciences, Jahad square, Urmia, West Azarbayjan, Iran. A

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5714615463

Approval date

2019-01-26, 1397/11/06

Ethics committee reference number

IR.UMSU.REC.1397.416

Health conditions studied

1

Description of health condition studied

Abdominal and Thoracic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score

Timepoint

At the beginning of study and then every 6 hours up to 48 hours

Method of measurement

NIPS (Neonatal Infant Pain Scale) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:IV Acetaminophen !0 mg/kg every 6 hours up to 48 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari University hospital, Urmia University of Medical sciences and Namazi hospital of Shi

Full name of responsible person

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia University of Medical Sciences
Proportion provided by this source
10
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available