

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparing the time of extubation, postoperative apnea incidence, and the quality of perioperative analgesia in infants scheduled for pyloromyotomy-intravenous bolus fentanyl vs rectal acetaminophen

Protocol summary

Study aim

Comparing the time of extubation, postoperative apnea incidence, and the quality of perioperative analgesia in infants scheduled for pyloromyotomy- intravenous bolus fentanyl vs rectal acetaminophen

Design

There are two groups in this research; in the first group we used Fentanyl as a pain relief medicine and in the second group we used rectal Acetaminophen. This study is a double blind study .

Settings and conduct

This study was a randomized double-blind controlled trial and was conducted in Tabriz Children hospital.

Participants/Inclusion and exclusion criteria

Infants witch are candidate for pyloromyotomy (open surgery) and do not have any other disease .

Intervention groups

24 infants with dx Hypertrophic Pyloric Stenosis which are candidate for pyloromyotomy are divided into two groups; in fentanyl group fentanyl (1µg/kg) and Midazolam will be used as a pain relief and in acetaminophen group for this purpose rectal acetaminophen (40mg/kg) will be used 20-30 min before Midazolam .

Main outcome variables

Knowing that patients with Hypertrophic Pyloric Stenosis are at risk of having a long recovery and apnea after surgery; deleting the drug that helps this effect like Fentanyl and replacing it with drugs like Acetaminophen witch dose not have this effect will be useful .

General information

Reason for update

Acronym

HPS

IRCT registration information

IRCT registration number: **IRCT20180726040601N1**

Registration date: **2018-09-24, 1397/07/02**

Registration timing: **retrospective**

Last update: **2018-09-24, 1397/07/02**

Update count: **0**

Registration date

2018-09-24, 1397/07/02

Registrant information

Name

Behzad Aliakbari Sharabiani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3330 2648

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-02-19, 1395/12/01

Actual recruitment end date

2018-08-23, 1397/06/01

Trial completion date

2018-08-23, 1397/06/01

Scientific title

Comparing the time of extubation, postoperative apnea incidence, and the quality of perioperative analgesia in infants scheduled for pyloromyotomy-intravenous bolus

fentanyl vs rectal acetaminophen

Public title

Comparing the time of extubation, postoperative apnea incidence, and the quality of perioperative analgesia in infants scheduled for pyloromyotomy- Intravenous bolus fentanyl vs rectal acetaminophen

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Infants with Hypertrophic Pyloric Stenosis Having no other problem

Exclusion criteria:

Age more than 2 months Weight less than 2.5 kg
Preterm labor Serum Hg less than 10mg/dl Serum bicarbonate more than 30mmol/l Serum pH more than 55mmol/L Using muscle relaxants

Age

From **10 days** old to **2 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Using online program:

URL:<http://WWW.stat.vbc.ca/nrolin/statssize/bz.htmf>

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research patients and health care providers and analyzers were not aware of choosing people .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz university of medical sciences

Street address

Children hospital of Tabriz - Sheshgelan Ave

City

Tabriz

Province

East Azarbaijan

Postal code

1998134753

Approval date

2018-09-15, 1397/06/24

Ethics committee reference number

IR.TBZMED.REC.1397.511

Health conditions studied

1

Description of health condition studied

Hypertrophic Pyloric Stenosis

ICD-10 code

P00-P96

ICD-10 code description

Digestive system disorders of fetus and newborn

Primary outcomes

1

Description

Knowing that patients with Hypertrophic Pyloric Stenosis are at risk of long recovery and apnea after surgery, deleting drugs that cause this effect like Fentanyl and replacing it with Acetaminophen witch dose not have this effect will be useful .(in case of having same pain relief effect) . in both groups the time of discharging from recovery and the number of apneas that happens in recovery after extubation will be recorded and the effects of this two drugs will be compared at the end .

Timepoint

In Fentanyl group we use Fentanyl as a pain relief with Midazolam and in Acetaminophen group we use rectal Acetaminophen 20-30 min before Midazolam .

Method of measurement

Recovery time with watch -Apnea with pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Infants with Hypertrophic Pyloric Stenosis witch are candidate for surgery ; in this group we use Fentanyl as a pain relief . in Fentanyl group we will use Fentanyl (1µg/kg) with Midazolam .in both groups the time of discharge from recovery and the number of apneas that happened in recovery will be written .

Category

Prevention

2

Description

Intervention group: Infants with Hypertrophic Pyloric Stenosis witch are candidate for surgery ; in this group we use rectal Acetaminophen as a pain relief. in acetaminophen group we will use rectal Acetaminophen (40mg/kg) before Midazolam .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Children hospital in Tabriz

Full name of responsible person

Behzad Aliakbar Sharabiani

Street address

Children hospital of Tabriz - Sheshgelan Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hasan Soleimanpour

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Tabriz university of medical science-research department-Golgasht Ave .

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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

Tabriz University of Medical Sciences

Proportion provided by this source

100

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

Tabriz University of Medical Sciences

Full name of responsible person

Behzad Aliakbar Sharabiani

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Behzad Aliakbar Sharabiani

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

Tabriz University of Medical Sciences

Full name of responsible person

Sahar Akbari

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the information will be shared after hidden the names

When the data will become available and for how long

It will be reachable after publish.

To whom data/document is available

All the information will be reachable for researchers .

Under which criteria data/document could be used

No condition .

From where data/document is obtainable

Children hospital of Tabriz.

What processes are involved for a request to access data/document

It will be reachable after publish

Comments