

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Assessing the effect of fetal position on the severity of pain during chest tube removal in neonates undergoing open-heart surgery

Protocol summary

Study aim

Assessing the effect of fetal position on severity of pain during chest tube removal in neonates undergoing open heart surgery

Design

To calculate the sample size, the Altman Nomogram was used. Considering , the sample size was calculated for each group of 30 people.

Settings and conduct

After obtaining the code of ethics from the Joint Ethics Committee from the Faculty of Nursing and Rehabilitation and the coordination of the officials of the Center for the Medical of Children's Hospital, a researcher in the Department of open heart Surgery of Neonatal Hospitals

Participants/Inclusion and exclusion criteria

Inclusion criteria: Complete the informed consent form for the neonates in the parent's research Infants 1 to 28 days Weight 2500 to 4000 grams Separated from mechanical ventilation Have a chest tube Exit criteria: - Infants with a prohibition (such as infants with chest infection and forbidden positions) - Infants who have syndrome of deprivation of the substance (babies who receive opioed for more than 7 to 10 days often find physiological tolerance and require increased levels of sleep apnea and analgesics to achieve optimal effects)'

Intervention groups

Receiving morphine by intervention and control group Provide an embryo position to the intervention group's infants The recording of hemodynamic symptoms in both groups by neonatal infant pain scale (NIPS)

Main outcome variables

Morphine Fetal position

General information

Reason for update

Acronym

FPT

IRCT registration information

IRCT registration number: **IRCT20181028041482N1**

Registration date: **2018-12-13, 1397/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-13, 1397/09/22**

Update count: **0**

Registration date

2018-12-13, 1397/09/22

Registrant information

Name

Somayeh Ashtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5537 7749

Email address

s_ashtari24@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-05-31, 1398/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of fetal position on the severity of pain during chest tube removal in neonates undergoing open-heart surgery

Public title

Assessing Fetal position in neonates undergoing open-heart surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Neonates with 1 to 28 days old neonates with 2500 to 4000 grams weight neonates extubed of ventilator neonates with chest-tube completion of consent form by parents

Exclusion criteria:

Neonates who have a prohibition of positioning (such as neonates with chest infection) Neonates with drug deprivation syndrome

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **30**

30 neonates in the intervention group and 30 neonates will be in the control group.

Randomization (investigator's opinion)

Randomized

Randomization description

method of randomization: Simple randomization unit of

randomization: Individual tools used in randomization:

flip the coin random sequence: single Allocation

concealment: single-blind

Blinding (investigator's opinion)

Single blinded

Blinding description

The parents of neonates were in the course of receiving their newborns' treatment, but they were not informed with either interventional or control groups, and thus single-blind study. In addition, neonatal nurses were not aware of the presence of newborns in the control or intervention group. The doctor in charge of removing the chest tube did not know the type of infant group.

Placebo

Not used

Assignment

Single

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

Tehran University of Medical Sciences, Qodse Ave, keshavarze Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-10-27, 1397/08/05

Ethics committee reference number

(IR.TUMS.FNM.REC.1397.136 (5/8/97

Health conditions studied

1

Description of health condition studied

Assessing the effect of fetal position on severity of pain during chest tube removal in neonates undergoing open heart surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of pain

Timepoint

Before intervention, During the intervention , 5 minutes after intervention

Method of measurement

NIPS(Neonatal infant pain scale)

Secondary outcomes

1

Description

Severity of pain score

Timepoint

Before intervention, During the intervention ,5 minutes after intervention

Method of measurement

Neonatal infant pain Scale

2

Description

Fetal of position

Timepoint

Before intervention - during intervention - 5 minutes after intervention

Method of measurement

NIPS(Neonatal infant pain scale)

Intervention groups

1

Description

Intervention group: Neonates in the intervention group, in addition to the administration of 0.05 mg of morphine 20 minutes prior to the removal of the chest tube, the neonate is placed by the nurse trained in the fetal position and the chest tube is given by the physician who is for all Neonates of the two fixed groups are removed and the physiological signs of pain (heart rate-respiration and blood oxygen saturation) and neonatal pain infant scale (NIPS) before and immediately after removal of The chest tube is examined and recorded 5 minutes after removing the chest tube.

Category

Treatment - Drugs

2

Description

Control group:Neonates in the intervention group, in addition to the administration of 0.05 mg of morphine 20 minutes prior to the removal of the chest tube,and the chest tube is given by the physician who is for all Neonates of the two fixed groups are removed and the physiological signs of pain (heart rate-respiration and blood oxygen saturation) and neonatal pain infant scale (NIPS) before and immediately after removal of The chest tube is examined and recorded 5 minutes after removing the chest tube.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Somayeh Ashtari

Street address

Children's Medical Center, Qarib Street

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Tehran

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1194815814

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Email

s_ashtari24@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Doctor Taqi zade

Street address

Faulty of Nursing Midwifery, West Nosrat St, Tohid square

City

Tehran

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1417653761

Phone

+98 21 6105 4431

Email

tums_edu@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Somayeh ashtari

Position

Master's student of neonatal intensive care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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No. 14, Riahi Alley, Barzegar Alley, Amirieh ave, Valie asr Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Somayeh Ashtari

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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