

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of pain and physiological indices in two ways of blood sampling from vein hand and vein head in premature infants with gestational age 32-28 weeks

Protocol summary

Summary

This study is a cross-over clinical trial which will be conducted with the aim of comparing the pain and physiological changes in two methods of blood sampling from the vein of head and the vein of hand in healthy preterm infants with 28-30 weeks and 30-32 weeks gestational age. Forty samples in two groups would be studied. In the first group, initial blood sampling will be done through the vein of hand and the further blood sampling in the next day will be done through the vein of head. In the second group of infants, blood sampling will be done in reverse. The pain score will be measured. To assess the physiological parameters including heart rate and oxygen saturation, the monitor would be used. Recording time of interventions will be 2 minutes before to 6 minutes after blood sampling.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042513691N6**
Registration date: **2016-07-25, 1395/05/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-25, 1395/05/04

Registrant information

Name

Mohammad Arshadi Bostanabad

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 6770

Email address

arshadi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences-faculty of Nursing and Midwifery

Expected recruitment start date

2016-04-01, 1395/01/13

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of pain and physiological indices in two ways of blood sampling from vein hand and vein head in premature infants with gestational age 32-28 weeks

Public title

The effects of blood sampling place on pain and Physiological indices of premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age of 28-30 weeks and 30-32 weeks and appropriate weight for gestational age; need for venous blood sampling in 4 to 8 days after birth; absence of congenital malformations and skin lesions on infants' hands or heads; the absence of blood disorders in mother's medical history; no history of smoking, alcohol and drug consumption by mothers during

pregnancy; not using of sedative from 12 hours before sampling; absence of Signs of Asphyxia; Stability of cardio-respiratory status; The intervals between two sampling times more than 24 hours; not receiving invasive interventions in the last six hours before blood sampling. Exclusion criteria: Parents' willing to study; multiple try for sampling; report of cerebral hemorrhage or brain abnormalities in cranial ultrasound; inappropriate quality of video to interpretation.

Age

From **4 days** old to **8 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

South Sharyati Ave.-Nursing and Midwifery Faculty

City

Tabriz

Postal code

5138947977

Approval date

2016-05-09, 1395/02/20

Ethics committee reference number

IR.TBZMED.REC.1395.136

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

M79.8

ICD-10 code description

Other specified soft tissue disorders

2

Description of health condition studied

Blood-sampling

ICD-10 code

Y84.9

ICD-10 code description

Medical procedure, unspecified

Primary outcomes

1

Description

pain

Timepoint

from 2 minutes to 6 minutes after blood sampling, Every 2 minutes

Method of measurement

Astrid Lindgren Children's Hospital Pain Scale

Secondary outcomes

1

Description

Heart rate , Blood oxygen saturation

Timepoint

from 2 minutes to 6 minutes after blood sampling, Every 2 minutes

Method of measurement

monitor device - Massimo 1600

Intervention groups

1

Description

Eligible infants who need for venous sampling in fourth to eighth days of their birth will be entered to study with convenience sampling method and recruited into two groups randomly. In the first group, first blood sampling through the vein of hand (Cephalic and Basilic veins and dorsal venous plexus back of the hand), the next day blood sampling through the vein of head (Superficial temporal vein in the side of the head and supratrochlear vein in the frontal part of the skull) will be use. For blood sampling from the vein of head, head circumference at the upper part of the eyebrows will be closed with a soft rubber band (Coban) with 1.5 cm of diameter, and for taking blood from the vein of the back of the hand, restriction will be performed via colleague's hand. Blood sampling will be carried out in direction of blood flow using Bio.Flon IV (No#24) with angle of 15 to 20 degrees in head vein and 25 to 45 degrees in hand vein. Trying to sampling will not be more than once. Pain score will be measured using pain scale. To investigate the physiological indices, a monitor device will be attached to the baby's foot, and heart rate and percentage of

arterial oxygen saturation, will be monitored throughout the study. In this study, to record the behavioral and physiological responses to pain two recording devices will be used. One of recording devices will be fixed to monitor to record the physiological responses and the next recording device will be focused the baby's face and limbs to record its behavioral responses.

Category

Other

2

Description

In Newborns of second group, blood sampling will be reversely; in which the first blood sampling will be done through the veins of head (Superficial temporal vein in the side of the head and supratrochlear vein in the frontal part of the skull), and the further blood sampling will be done through hand veins (Cephalic and Basilic veins and dorsal venous plexus back of the hand), in next day. For blood sampling from the vein of head, head circumference at the upper part of the eyebrows will be closed with a soft rubber band (Coban) with 1.5 cm of diameter, and for taking blood from the vein of the back of the hand, restriction will be performed via colleague's hand. Blood sampling will be carried out in direction of blood flow using Bio.Flon IV (No#24) with angle of 15 to 20 degrees in head vein and 25 to 45 degrees in hand vein. Trying to sampling will not be more than once. Pain score will be measured using pain scale. To investigate the physiological indices, a monitor device will be attached to the baby's foot, and heart rate and percentage of arterial oxygen saturation, will be monitored throughout the study. In this study, to record the behavioral and physiological responses to pain two recording devices will be used. One of recording devices will be fixed to monitor to record the physiological responses and the next recording device will be focused the baby's face and limbs to record its behavioral responses.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Zahra Pourashori

Street address

South Artesh Ave.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Rashidi

Street address

Daneshgah Ave. Tabriz University of Medical Sciences

City

Tabriz

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

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Arshadi Bostanabad Mohammad

Position

Assistant Professor

Other areas of specialty/work

Street address

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Fax

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arshadi@tbzmed.ac.irarshadi-m@yahoo.com

Web page address

Person responsible for updating data

Contact

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