

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of oral dextrose and facilitated tucking in reducing pain associated with arterial blood sampling in preterm infants

Protocol summary

Study aim

This study aimed to compare the efficacy of oral Dextrose and the use of facilitated tucking on the pain caused by blood sampling in preterm infants

Design

A randomized clinical trial with crossover design

Settings and conduct

Neonatal Intensive Care Unit (NICU) at Valiasr hospital in Tehran, Iran

Participants/Inclusion and exclusion criteria

Hospitalized neonates with gestational age 28-36 weeks who were anticipated to have at least six heel sticks during the NICU hospitalization

Intervention groups

No pain relief method, oral dextrose, and facilitated tucking

Main outcome variables

Pain measured by The Premature Infant Pain Profile (PIPP)

General information

Reason for update

Due to the long time of hospitalization of neonates in the NICU, the recruitment of three parallel groups was very difficult. Also, the response of children to pain is very different and the comparison of three methods in all subjects can eliminate these differences, therefore considering the non-invasive nature of interventions (Oral Dextrose and Positioning), both methods were used by a cross-over method. Three groups with twenty subjects were included in the study with different orders in interventions (Control, Oral Dextrose, and Positioning). The age limit inclusion criteria changed from 32 -36 weeks based on the definition of the premature neonate.

Acronym

IRCT registration information

IRCT registration number: **IRCT201408029568N9**

Registration date: **2014-09-08, 1393/06/17**

Registration timing: **prospective**

Last update: **2019-10-16, 1398/07/24**

Update count: **1**

Registration date

2014-09-08, 1393/06/17

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2357

Email address

mfnhrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Maternal and Fetal Research Center

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

2015-03-14, 1393/12/23

Actual recruitment end date

2016-11-20, 1395/08/30

Trial completion date

2017-02-15, 1395/11/27

Scientific title

The effect of oral dextrose and facilitated tucking in reducing pain associated with arterial blood sampling in preterm infants

Public title

Effect of pain relief methods blood sampling pain in newborns

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Absence of asphyxia at birth based on infant records
Birth age of 2-28 days Anticipated to have at least six heel sticks during the NICU hospitalization No administration of sedatives relaxants, antiepileptic, or analgesic in 24 hours before every study session Born to mothers with no history of addiction to substances Not having any acute condition which required more critical care surgery Not using of sedative, relaxants, antiepileptic, or analgesic drugs

Exclusion criteria:

Age

From **28 months** old to **36 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **3**

Control, Oral Glucose, facilitated tucking

Actual sample size reached: **60**

More than 1 sample in each individual

Actual sample size in each individual: **3**

Control, Oral Glucose, facilitated tucking

Randomization (investigator's opinion)

Randomized

Randomization description

Infants with inclusion criteria were randomly allocated to three groups (A, B and C) by permutated blocks of six.

Six blocks were defined (ABC, ACB, BAC, BCA, CAB and CBA) and a number from 1 to 6 were assigned to each block.

By rolling dice the sequence of blocks was determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistician was not present in patient enrollment, and the data collector was not involved in data analysis

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences/Research Center for Maternal and newborn baby

Street address

Research Center for Maternal and newborn baby- Second Floor-Asr Hospital-Gharib Street- Keshavarz Street

City

Tehran

Province

Tehran

Postal code

1416753955

Approval date

2014-05-19, 1393/02/29

Ethics committee reference number

25966

Health conditions studied

1

Description of health condition studied

Acute Pain

ICD-10 code

R52.0

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

before of intervention, during and after of intervention

Method of measurement

Premature Infant Pain Profile

Secondary outcomes

1

Description

Feasibility

Timepoint

After Intervention

Method of measurement

Questioning about simplicity and the applicability

Intervention groups

1

Description

Intervention 1/ Oral Dextrose solution, 0.5 ml of 50 % dextrose by a syringe 2 minutes before the procedure

Category

Other

2

Description

Intervention 2/ The facilitated tucking placing infants on their side, with their back gently bent, and their legs were in a flexion angle of greater than 90 degrees

Category

Other

3

Description

Control, conducting procedure based on hospital protocol without any pain relief intervention except the application of gentle touching and verbal comfort

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Athareh Ranjbar

Street address

Chamran, East, Highway, Baqerkhan St

City

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Postal code

1419733141

Phone

+98 21 6659 1316

Email

athare_ranjbar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mamak Shariat

Street address

Second Floor, Asr Hospital, Imam Khomeini Complex, Gharib Street, Keshavarz Blv

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mshariat@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/Asr hospital

Full name of responsible person

Athareh Ranjbar

Position

Master of Nursing/ Health Education Supervisor

Latest degree

Master

Other areas of specialty/work

Nursery

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nikoo Niknafs

Position

Assistant Professor/Neonatologist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Web page address**Fax****Email**

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Web page address**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

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

Title and more details about the data/document

All of the individual participant data collected during the
trial, after deidentification

**When the data will become available and for how
long**

Immediately following publication. No end date.

To whom data/document is available

Anyone who wishes to access the data.

Under which criteria data/document could be used

To gain access, data requestors will need to sign a data
access agreement. The data is available for any purpose.

From where data/document is obtainable

All applications should be sent to
athare_ranjbar@yahoo.com

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

All requests will be answered within a maximum of one
month by email.

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

Tehran University of Medical Sciences/Maternal Fetal
Neonatal Research Center

Full name of responsible person

Athareh Ranjbar

Position

Master of nursing/ Health Education Supervisor

Latest degree

Master

Other areas of specialty/work

Nursery

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