

# 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

Tehran

##### Province

Tehran

##### 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

##### City

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##### Province

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##### Postal code

1419733141

##### Phone

+98 21 6659 1316

##### Email

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

##### Street address

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

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##### Province

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##### Postal code

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##### Phone

+98 21 6694 0020

##### Fax

##### Email

athare\_ranjbar@yahoo.com

##### 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

**Street address**

Second Floor, Asr Hospital, Imam Khomeini  
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nikoo.niknafs@gmail.com

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

athare\_ranjbar@yahoo.com

**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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