

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jul 2026

### Comparison survey between breast feeding and Sucrose on pain relief and physiological parameters during capillary sampling in neonates: A randomized controlled trial

#### Protocol summary

##### Summary

Objective: The aim of this study is to compare effects of breast feeding and sucrose in reducing pain during minimally invasive procedures in neonates such as capillary sampling. Design: Ninety-five consecutive infants who refer to Razavi Hospital, Mashhad for routine neonates screening will be selected. Participants: Ninety-five consecutive infants who underwent capillary sampling due to neonatal screening. Written informed consent should be filled by both parents. All the infants should meet inclusion criteria such as born at gestational age of  $\geq 37$  weeks; aged between 1-5 days and 5 minutes APGAR score of more than 7. Setting and interventions: Newborn infants will be divided to three groups: Group A: 2 ml sterile water as placebo; Group B: 2 ml sucrose 25% and Group C: breast feeding in kangaroo care. ). Main outcome measures: Physiologic parameters including heart rate, blood pressure and capillary oxygen saturation level will be recorded during the sampling and 3 minutes after the procedure. NIPS score as well as physiologic values will be recorded by the investigator in each minute. Final result of NIPS score and physiologic values are the mean of given data for each 1-minute observation. Analysis will be done by means of SPSS.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014101919589N1**

Registration date: **2014-12-12, 1393/09/21**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-12-12, 1393/09/21

##### Registrant information

###### Name

Emadodin Darchini-Maragheh

###### Name of organization / entity

Mashhad University of Medical Sciences, Mashhad, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3878 6692

###### Email address

darchinime861@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research, Mashhad university of medical sciences, Mashhad, Iran

##### Expected recruitment start date

2014-12-22, 1393/10/01

##### Expected recruitment end date

2015-01-20, 1393/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison survey between breast feeding and Sucrose on pain relief and physiological parameters during capillary sampling in neonates: A randomized controlled trial

##### Public title

Effect of breast feeding and Sucrose on pain relief in

neonates

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: filling the written informed consent by both parents; born at gestational age of  $\geq 37$  weeks; aged  $>24$  hours (between 1-5 days); has 5 minutes APGAR score of  $\geq 7$  Exclusion criteria: Medically instable infants; those who had received sedatives or analgesics in the past 48 hours; infants who had received naloxone in the previous 24 hours; preterm and Low Birth Weight (LBW) infants; Those who had been fed in the past 30 minutes

**Age**  
From **1 day** old to **5 days** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **95**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Ethics committee, central building of Mashhad University of Medical Sciences (Ghorshi building), Daneshgah avenue, Mashhad, Iran

##### City

Mashhad

##### Postal code

#### Approval date

2014-10-19, 1393/07/27

#### Ethics committee reference number

938052

## Health conditions studied

### 1

#### Description of health condition studied

Acute pain

#### ICD-10 code

R52.0

#### ICD-10 code description

pain, not elsewhere classified

## Primary outcomes

### 1

#### Description

heart rate

#### Timepoint

each minute until 3 minutes after sampling

#### Method of measurement

cardiac monitoring

### 2

#### Description

blood pressure

#### Timepoint

each minute until 3 minutes after sampling

#### Method of measurement

cardiac monitoring

### 3

#### Description

capillary oxygen saturation level

#### Timepoint

each minute until 3 minutes after sampling

#### Method of measurement

cardiac monitoring

### 4

#### Description

pain alleviating

#### Timepoint

each minute until 3 minutes after sampling

#### Method of measurement

neonatal infants pain scale score (NIPS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

2 ml of sterile water as placebo will be prepared and syringed in anterior part of the tongue 2 minutes before sampling

#### Category

Placebo

## 2

### Description

2 ml sucrose 25% will be prepared in advance and syringed in anterior part of tongue 2 minutes before sampling

### Category

Treatment - Other

## 3

### Description

Infants will be breastfed in kangaroo care. Breastfeeding will be started 2 minutes before sampling and continue during the sampling. Infants are dressed, thus there is no skin to skin contact with mother. Mothers are not allowed to speak with their babies nor swaddle them.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Razavi Hospital, NICU

#### Full name of responsible person

Dr. Anahita Alizadeh-Ghamsari

#### Street address

Azadi square, Ferdowsi university campus, medical university research center

#### City

Mashhad

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice-chancellor for research- Mashhad University of Medical Sciences, Mashhad, Iran

#### Full name of responsible person

Dr. Tafaghodi

#### Street address

Research Department (Ghoreyshi building) - 2nd floor - Daneshgah Avenue

#### City

Mashhad

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Vice-chancellor for research- Mashhad University of Medical Sciences, Mashhad, Iran

### 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

#### Name of organization / entity

Ferdowsi university campus, College of medicine

#### Full name of responsible person

Emadodin Darchini-Maragheh

#### Position

Medical student

#### Other areas of specialty/work

#### Street address

Medical Toxicology Research Center, Ferdowsi university campus, Azadi square

#### City

Mashhad

#### Postal code

#### Phone

+98 51 3800 2463

#### Fax

#### Email

darchinime861@mums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Medical toxicology research center, Imam Reza hospital, Imam Reza square, Mashhad

#### Full name of responsible person

Dr Anahita Alizadeh-Ghamsari

#### Position

MD, Pediatrician, fellowship of medical toxicology

#### Other areas of specialty/work

#### Street address

Imam Reza Hospital, Medical Toxicology Research Center (MTRC)

#### City

Mashhad

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+98 51 3880 2463

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alizadehan@mums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Emadodin Darchini-Maragheh

**Position**

medical student

**Other areas of specialty/work**

**Street address**

Medical toxicology research center, Ferdowsi  
university campus, Azadi square, Mashhad

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3800 2463

**Fax**

**Email**

darchinime861@mums.ac.ir

**Web page address**

## 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*