

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparison the effect of pacifier and sucrose (non-medical method ) in pain management In the neonatal intensive care unit

#### Protocol summary

##### Summary

Aim: Compare the effect of pacifier with sucrose (non-medical method) in pain management in the neonatal intensive care unit. In this non-randomized clinical trial, 40 infants were selected. Inclusion criteria: Term infants (Gestational age 38 to 42 weeks); normal birth weight (2500 to 4000 grams), fifth minute APGAR score  $\geq 7$ . Exclusion criteria: Congenital defects; Infection and wound at the site of venipuncture; Serious disease symptoms such as septicemia after 24 hours from the test; unsuccessful try in venipuncture. In the first intervention, nothing will be done before the venipuncture for pain control. Newborn pain will be measured before and at the venipuncture time and after three minutes of venipuncture. Next time, 2 minutes before venipuncture a proportional pacifier will be put in baby's mouth. Pain in newborns will be measured after 2 minutes, at the time of venipuncture and after three minutes of venipuncture (actually three times). Next time, 2 cc of 24% sucrose solution will be given to the same baby. The pain will be measured three times (eg. after 2 minutes, at the time of venipuncture and after three minutes of venipuncture)

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092329921N1**

Registration date: **2017-07-01, 1396/04/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-01, 1396/04/10

##### Registrant information

##### Name

Firoozeh Darvishi

##### Name of organization / entity

Shahid Bbehsheti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7704 5639

##### Email address

fi.darvishi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Researcher

##### Expected recruitment start date

2016-06-30, 1395/04/10

##### Expected recruitment end date

2016-11-30, 1395/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of pacifier and sucrose (non-medical method ) in pain management In the neonatal intensive care unit

##### Public title

Comparison the effect of pacifier and sucrose (non-medical method) in pain management.

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Term infants (Gestational age 38 to 42 weeks); normal birth weight (2500 to 4000 grams), fifth minute APGAR score  $\geq 7$ . Exclusion criteria: Congenital defects; Infection and wound at the site of venipuncture;

Serious disease symptoms such as septicemia after 24 hours from the test; unsuccessful try in venipuncture.

## Age

From **1 day** old to **1 month** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti University of Medical Sciences And Health Services.

##### Street address

Velenjak, 7th Floor, Bldg No. 2 SBUM, SARabi Ave.

##### City

Tehran

##### Postal code

1983969411

#### Approval date

2016-06-21, 1395/04/01

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1395.226

## Health conditions studied

### 1

#### Description of health condition studied

does not have

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

PAIN

## Timepoint

before intervention, during intervention, before intervention

## Method of measurement

NIPS

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Use of routine care, 2 minutes before intervention.

#### Category

Prevention

### 2

#### Description

Use of 2 ml of sucrose 24%, 2 minutes before intervention.

#### Category

Treatment - Drugs

### 3

#### Description

used of pacifier 2 minutes before intervention.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mofid hospital

##### Full name of responsible person

Maryam Momeny

##### Street address

Mofid Hospital, Shariati street, Tehran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mofid Hospital

##### Full name of responsible person

Mohamad Kazemiyan

##### Street address

Mofid Hospital, Shariati street, Tehran

##### City

Tehran

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
 Yes  
**Title of funding source**  
 Mofid Hospital  
**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**  
 Mofid Hospital  
**Full name of responsible person**  
 Nazanin Keshavarz  
**Position**  
 MS in student  
**Other areas of specialty/work**  
**Street address**  
 Mofid Hospital, Shariati Street, Tehran  
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 Tehran  
**Postal code**  
 1546815514  
**Phone**  
 +98 21 2222 7021  
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**Email**  
 nazanin8059@yahoo.com  
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 www.mch.sbm.ac.

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
 Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
 Fateme Alaei  
**Position**  
 Phd of nursing

**Other areas of specialty/work**  
**Street address**  
 Daneshjo Blvd., Shahriari Sq., Yemen St., Chamran Highway, Tehran  
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 1985717443  
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 falaekarahroudy@sbmu.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
 Mofid Hospital  
**Full name of responsible person**  
 Fateme ghafari  
**Position**  
 Nurse  
**Other areas of specialty/work**  
**Street address**  
 Shariati street, mofid hospital, Tehran  
**City**  
 Tehran  
**Postal code**  
**Phone**  
 +98 21 2222 7021  
**Fax**  
**Email**  
 t.momeni@sbmu.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