

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 ≥ 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 Bbeheshi 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 ≥ 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
City
 Tehran
Postal code
 1546815514
Phone
 +98 21 2222 7021
Fax
 +98 21 2222 0254
Email
 nazanin8059@yahoo.com
Web page address
 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
City
 Tehran
Postal code
 1985717443
Phone
 +98 21 8865 5366
Fax
 +98 21 8820 2521
Email
 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