

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparisional Survey the Effect of Sucrose oral Solution (20%) with Sterile Water on Severity of Pain During Venipuncture in Premature Neonates Who were Admitted to Motahhari Educational Center of Urmia in 2019 to 2020

Protocol summary

Study aim

Determine of the Effect of Sucrose oral Solution (20%) with Sterile Water on Severity of Pain During Venipuncture in Premature Neonates Who were Admitted to Motahhari Educational Center of Urmia in 2019 to 2020

Design

A randomized controlled clinical trial with parallel, double-blind, randomized by the random number table method

Settings and conduct

In the Maternity ward of Shahid Motahari Hospital of Urmia, 150 infants will be randomly assigned to three groups a, b and c. Two minutes before the aqueous injection of group a 20% sucrose oral solution, group b will receive distilled water and group c will receive no intervention. Neonatal behavioral response will be assessed before, 2 minutes and 7 minutes after venipuncture.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Ages 2 to 5 days after birth First minute Apgar score of 7-10 No painful interventions such as resuscitation and blood sampling etc. Exclusion criteria: Maternal opioid use Infant's heart, respiratory and developmental problems

Intervention groups

Infants receiving sucrose solution 20% Infants receiving sterile water

Main outcome variables

Neonatal behavioral response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200225046615N1**

Registration date: **2020-04-07, 1399/01/19**

Registration timing: **prospective**

Last update: **2020-04-07, 1399/01/19**

Update count: **0**

Registration date

2020-04-07, 1399/01/19

Registrant information

Name

Hosein Habibzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4961

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparisional Survey the Effect of Sucrose oral Solution (20%) with Sterile Water on Severity of Pain During

Venipuncture in Premature Neonates Who were Admitted to Motahhari Educational Center of Urmia in 2019 to 2020

Public title

The Effect of Sucrose oral Solution (20%) with Sterile Water on Severity of Pain During Venipuncture in Premature Neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Births at 2 to 4 weeks of gestation Weights of 1.5 kg and more Ages 2 to 5 days after birth First minute Apgar score of 7-10 No painful interventions such as resuscitation and blood sampling etc

Exclusion criteria:

Breastfeeding 5 minutes before venipuncture Take acetaminophen on the same day and Naloxone or Phenobarbital in the last 7 hours Maternal opioid use Infant's heart, respiratory and developmental problems

Age

From **1 day** old to **3 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method was block randomization and from among 200 eligible preterm infants that met the inclusion criteria, 150 infants were selected randomly using www.randomizer.org. Then, three control groups, Sucrose, 20% and oral Solution were considered, so that we randomly placed the tip of the pen on the Random letter table. If the letter c came, the baby in the control group. And if the letter A came, the premature baby would be in the distilled water group, and this would continue until 50 infants were completed for each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each of the Sucrose oral Solution (20%) and Sterile Water, will be placed in the same container with codes 1 and 2 and the researcher and statistical analyst will have no knowledge of the type of solution, and only the nurse who will administer the solution to infants. The researcher will be aware of the solutions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Approval date

2019-12-18, 1398/09/27

Ethics committee reference number

IR.UMSU.REC.1398.347

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Neonatal behavioral response

Timepoint

2 and 7 minutes after oral administration

Method of measurement

Neonatal Infant Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Two minutes before venipuncture, give 20 ml of infant 20% sucrose solution

Category

Treatment - Drugs

2

Description

Intervention group: Two minutes before the infant is fed a half-ml solution of distilled water to infants

Category

Treatment - Drugs

3

Description

Control group: No oral solution

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari University Hospital

Full name of responsible person

Maryam Salamatbakhsh

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Shahid Motahari Hospital, Kashani St., Urmia, I.R.IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Hosein Habibzadeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The findings of the study will be published and published in paper form

When the data will become available and for how long

After completing the study and writing the article

To whom data/document is available

All researchers and interested people

Under which criteria data/document could be used

Published in the form of an article and after accepting and publishing the article in a prestigious journal

From where data/document is obtainable

Scientific databases for article search

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

If there is a request for the study results prior to the publication of the article, the research team will provide the results.

Comments