

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of sucrose for relieving lumbar puncture pain in neonates of Kamali hospital in Karaj, randomized clinical trial

Protocol summary

Study aim

Determining the efficacy of sucrose for relieving lumbar puncture pain in neonates of Kamali hospital, randomized clinical trial

Design

A randomized controlled trial with a control group, with parallel groups, the double-blind, phase 3, will be conducted on 60 LP candidate infants. Pre-randomization list with <https://www.sealedenvelope.com/simple-randomiser/v1/lists> The use of web software will be provided with an email address.

Settings and conduct

the study will be performed on neonates who are candidates for lumbar puncture in Kamali hospital in Karaj city.

Participants/Inclusion and exclusion criteria

age under 28 days, being the term

Intervention groups

the precipitant neonates will divide into two groups, one group will receive 2cc of oral sucrose 25% and the other group will receive 2cc of oral Distilled water

Main outcome variables

NIPS (neonatal infant pain score) and physiological criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220703055360N1**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**

Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Sina Mashayekhi Poor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3464 6926

Email address

sinamashayekhi13760911@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of sucrose for relieving lumbar puncture pain in neonates of Kamali hospital in Karaj, randomized clinical trial

Public title

The efficacy of sucrose for relieving lumbar puncture pain in neonates of Kamali hospital in Karaj, randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

being term (in neonates) age under 28 days no fever

(body temperature under 38 centigrade) no feeding
before 30 minutes before studying
Exclusion criteria:
having congenital anomalies having metabolic diseases

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Considering that the study participants are neonates, the study is double-blinded. In order to randomize the studied groups, using the block randomization method with size Unmatched blocks for assigning samples to one of the two desired intervention groups (the group we give sucrose to) and the control group (the group to which we give sterile distilled water) will be used. Pre-randomization list with <https://www.sealedenvelope.com/simple-randomiser/v1/lits> Using web software with the email address will be prepared and the researcher who is not involved in the patient selection and allocation process will have access to this form. Block sizes 2, 4, and 6 will be selected.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz university of medical science

Street address

Beheshti Ave, Seyed-Alshohada Ave, Kamali hospital

City

Karaj

Province

Alborz

Postal code

3134877179

Approval date

2023-01-18, 1401/10/28

Ethics committee reference number

IR.ABZUMS.REC.1401.275

Health conditions studied

1

Description of health condition studied

pain control

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

neonatal infant pain score (NIPS)

Timepoint

before, first minute and third minute

Method of measurement

observation of neonate and Measurement of NIPS and physiologic criteria. This criterion includes examining facial changes, crying, breathing pattern, motor activity, and arousal state. Facial changes include two points, if there are loose muscles and a relaxed face, zero points are given, and if there are any of the changes such as contraction of facial muscles, pulling together eyebrows, chin, or jaw, one point is given. The quality of crying is also given three points including zero points in case of no crying, point one in case of brief and intermittent crying, and point two in case of excessive, continuous, loud crying. Breathing status includes zero scores in case of any change in the normal breathing status such as holding the breath, breathing faster than usual, and irregular breathing. condition of upper and lower limbs; Each of them will receive a score of zero in the presence of muscle stiffness and accidental movements of the limbs, and a score of one in the presence of muscle stiffness and rapid bending and straightening movements; and to the state of consciousness; If there is no change in sleeping or waking state, a score of zero is given, and if there is any restlessness, a score of one is given. The physiological criteria (O2 saturation) studied include heart rate, breathing rate, and blood oxygen saturation percentage

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group that is given 2 cc of oral

25% sucrose
Category
Treatment - Drugs

2

Description
Control group: The group that is given 2 cc of distilled water
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali hospital, Karaj city
Full name of responsible person
Sina Mashyaekhi Poor
Street address
Beheshti Ave, Seyed Alshohada Ave, Kamali hospital
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sinamashayekhi13760911@gmail.com
Web page address
<https://www.kamali.abzums.ac.ir>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Science
Full name of responsible person
Deputy of research and technology
Street address
Bu Ali Ave, Alborz university of medical science
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sinamashayekhi13760911@gmail.com
Web page address

<https://abzums.ac.ir>

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz University of Medical Science
Proportion provided by this source
70
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
Alborz University of Medical Science
Full name of responsible person
Alireza Jashni Motlagh
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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