

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effect of sucrose and glucose on neonatal pain during invasive procedures in the neonatal intensive care unit of Kashan Beheshti Hospital

Protocol summary

Study aim

Comparative study of the effect of sucrose and glucose on neonatal pain during invasive procedures in the neonatal intensive care unit of Kashan Beheshti Hospital

Design

Clinical trial with two parallel intervention groups, double blind, non- randomized, phase 2, on two groups of 30 people (total of 60 patients)

Settings and conduct

Neonatal intensive care unit of Kashan Beheshti Hospital. Two minutes before performing 3 invasive procedures, 0.1 to 2 cc of sucrose solution in group 1 and the same amount of glucose solution in group 2 will be used. The solutions will be sprayed on the anterior surface of the tongue.

Participants/Inclusion and exclusion criteria

Inclusion criteria: admitted infants into the intensive care unit; birth in weeks 27 to 40 weeks of gestation, presence of sucking reflex and swallowing. Exclusion criteria: feeding the baby 30 minutes before injection, receiving acetaminophen on the same day, heart, neurological and developmental problems, no of GAG reflex, maternal opioid use, naloxone or phenobarbital use in the last 48 hours.

Intervention groups

In the first group of the intervention, the amount of 0.1 to 2 cc of 24% sucrose solution and In the second intervention group, the same amount of 20% glucose will be used 2 minutes before performing 3 invasive procedures. The Neonatal Pain Scale will be used to assess pain.

Main outcome variables

Neonatal pain during invasive procedures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201004048918N1**

Registration date: **2020-11-02, 1399/08/12**

Registration timing: **retrospective**

Last update: **2020-11-02, 1399/08/12**

Update count: **0**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name

Mahin Safayee moghane

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5543 4038

Email address

mahin.safayee@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of sucrose and glucose on

neonatal pain during invasive procedures in the neonatal intensive care unit of Kashan Beheshti Hospital		East Jay St. - Purple - University Blvd.	
Public title	Comparison of the effect of sucrose and glucose on neonatal pain	City	Esfahan
Purpose	Treatment	Province	Isfahan
Inclusion/Exclusion criteria		Postal code	۸۱۵۵۱-۳۹۹۹۸
Inclusion criteria:	Hospitalization of infants in the neonatal intensive care unit Gestational age of 27 to 40 weeks Existence of swallowing and sucking reflex	Approval date	2020-09-19, 1399/06/29
Exclusion criteria:	Feed the baby 30 minutes before the injection Take acetaminophen on the same day Opioid use by the mother Existence of cardiorespiratory, developmental and neurological problems Lack of gag reflex Receive naloxone or phenobarbital in the last 48 hours	Ethics committee reference number	IR.IAU.KHUISF.REC.1399.173
Age	To 28 days old	Health conditions studied	
Gender	Both	1	
Phase	2	Description of health condition studied	
Groups that have been masked	- Participant - Care provider - Outcome assessor - Data analyser	Infants admitted to the hospital with respiratory problems, premature infants, low birth weight	
Sample size	Target sample size: 60	ICD-10 code	
Randomization (investigator's opinion)	Not randomized	ICD-10 code description	
Randomization description		Primary outcomes	
Blinding (investigator's opinion)	Double blinded	1	
Blinding description	The study is double-blind.Sucrose is indicated by code A and glucose by code B.Participants in this study and nurses who assist in gathering information are unaware of the type of solutions. Only the researcher knows the type of solutions.	Description	
Placebo	Not used	Reduce pain in infants	
Assignment	Parallel	Timepoint	
Other design features		Measurement of pain when performing 3 invasive procedures on infants.Includes venous venipuncture, arterial blood draw, lumbar puncture	
Secondary Ids	empty	Method of measurement	
Ethics committees		Use of infant pain measurement tools-pipp	
1		Secondary outcomes	
Ethics committee		empty	
Name of ethics committee	Islamic Azad University-Isfahan Branch (Khorasgan)	Intervention groups	
Street address		1	
		Description	
		Intervention group 1:The group receiving sterile sucrose 24% , which will be prepared as a package of 5 ml polyethylene ampoule from Shahid Ghazi Pharmaceutical Company located in Tabriz.And will be used orally with a syringe and without a needle head.2 minutes before the invasive procedure,An amount of 0.1 to 2 cc of 24% sucrose solution is injected on the anterior surface of the baby's tongue.The procedure is then performed and the pain score is measured.The maximum effect of sucrose is up to 5 minutes.If the procedure is prolonged, the dose can be repeated.	
		Category	
		Prevention	
		2	
		Description	
		Intervention group 2:The group receiving glucose.20%	

liquid glucose will be provided by Shahid Ghazi Pharmaceutical Company located in Tabriz and will be used orally using a needleless syringe. 2 minutes before the invasive procedure, 0.1 to 2 cc of glucose 20 solution is injected on the anterior surface of the baby's tongue. The procedure is then performed and the pain score is measured. The baby will be monitored for 30 seconds. The maximum effect of glucose is up to 5 minutes. If the procedure is prolonged, the dose can be repeated.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Mohammad Reza Sharif

Street address

Qutb Ravandi Blvd., Pezeshk Blvd.

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Kashan

Province

Isfahan

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Email

beheshtihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoumeh Tabatabai

Street address

Safaieh, Boulevard of the Unknown Martyrs

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YAZD

Province

Yazd

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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

Islamic Azad University

Proportion provided by this source

1

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

Islamic Azad University

Full name of responsible person

Maasoumeh Barkhordari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Safaei Mahin
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Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Police Square, Bustan Boulevard, 4 Shabnam
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Kashan
Province
Isfahan

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient information is confidential and non-disclosable.
No further information available.

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable