

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the effect of combination of touch and mother's voice with glucose 50% on pain reduction of Blood sampling in preterm infants

Protocol summary

Study aim

Comparison of the combined effect of maternal touch and sound with 50% glucose on reducing pain due to blood sampling in preterm infants

Design

The infants in the combined group received Jackson's sound and touch from the mother for 5 minutes. The mother would touch Jackson at the baby's bedside, whisper the previously mentioned lullaby, and draw blood at the same time. The Jackson protocol has key aspects of traditional Jackson (warm hands, gentle touch without pressure, and gentle hand movements) that are suitable for premature infants. In Jackson touch, the non-dominant hand is placed on the baby's back and the dominant hand is placed on the baby's chest and abdomen. Infants in the oral glucose group received 2 ml and blood sampling was performed after 2 minutes. The infants in the control group received routine care.

Settings and conduct

Premature infants referred to Ali Ibn Abitaleb Hospital in Rafsanjan from November 2016 to June 1400 were purposefully selected and randomly assigned to three equal groups of combination, oral glucose and control.

Participants/Inclusion and exclusion criteria

All premature infants weighing less than 2500 g, gestational age at birth at least 29 weeks and at most 36 weeks, lack of congenital anomalies, no intracranial hemorrhage or neurological problems, inability to take painkillers 24 hours a day They had arterial blood sampling and entered the study.

Intervention groups

The combined intervention of Jackson touch and maternal voice was performed on one group of infants and oral glucose in the other group and the control group did not receive any intervention.

Main outcome variables

Touching Jackson, mother's voice, oral glucose, pain intensity, premature infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211117053083N1**

Registration date: **2022-05-07, 1401/02/17**

Registration timing: **retrospective**

Last update: **2022-05-07, 1401/02/17**

Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name

Azam Heidarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

heidarzadehazam@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-16, 1399/08/26

Expected recruitment end date

2021-06-10, 1400/03/20

Actual recruitment start date

2020-11-16, 1399/08/26

Actual recruitment end date

2021-07-06, 1400/04/15

Trial completion date

2021-07-06, 1400/04/15

Scientific title

Comparison of the effect of combination of touch and mother's voice with glucose 50% on pain reduction of Blood sampling in preterm infants

Public title

"Investigation of the combined effect of maternal touch and voice on neonatal pain"; "Evaluation of the effect of 50% glucose on infant pain relief"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

weight less than 2500 g gestational age at birth at least 29 weeks and at most 36 weeks lack of congenital anomalies Failure to receive painkillers or sedatives within the previous 24 hours No need for arterial blood sampling Inequality of blood sampling in two blood samples no intracranial hemorrhage or neurological problems

Exclusion criteria:

Need a ventilator Need sedatives Failure to draw blood the first time

Age

From **203 days** old to **273 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Infants with inclusion criteria were randomly divided into three groups (A, B and C) with six alternate blocks. Six blocks (ABC, ACB, BAC, BCA, CAB and CBA) and a number between 1 and 6 were assigned to each block. The sequence of blocks was determined by rolling the dice.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the researcher was in charge of the intervention and one person entered the study as an outcome assessor who was not aware of the type of intervention in each group and a blind study was performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Jomhori Blvd

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Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.RUMS.REC.1397.263

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

Infant pain

Timepoint

Before and after the intervention

Method of measurement

Neonatal Infant Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The infants in the combined group received sound and Yakson touch from the mother for 5 minutes. The mother touched Yakson while the baby was in bed and while touching the lullaby she had already mentioned, she whispered and blood sampling was performed simultaneously. The Yakson protocol has key aspects of traditional Yakson (warm hands, gentle touch without pressure, and gentle hand movements) that are suitable for premature infants. In Yakson touch, the non-dominant hand is placed on the baby's back and the

dominant hand is placed on the baby's chest and abdomen

Category

Other

2

Description

Intervention group 2: Infants in the oral glucose group received 2 ml and blood sampling was performed after 2 minutes.

Category

Other

3

Description

Control group: The infants in the control group received routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb Hospital in Rafsanjan

Full name of responsible person

Parisa Shahmohammadipour

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Nurse Ave., Jomhori Blvd., Rafsanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Reza Vazirinejad

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Parisa Shahmohammadipour

Position

instructor

Latest degree

Master

Other areas of specialty/work

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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

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable