

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparing the effect of non-nutritional sucking and maternal voice on venous blood sampling pain in neonates

Protocol summary

Study aim

Comparison of non-nutritional sucking(NNS) methods and maternal voice on venous blood sampling pain in term infants with jaundice

Design

Clinical trial with control group, with parallel groups, block randomization using statistical software.

Settings and conduct

The study population was infants who were admitted to the neonatal ward of Imam Khomeini Hospital in Boroujerd with a diagnosis of physiological jaundice. The samples are randomly divided into three groups and are divided into three groups: NNS, maternal voice and control. In order to perform the intervention from before the start of blood sampling until after, in the NNS group, a pacifier is used and in the mother's voice group, the mother talks to the baby and in the control group, blood sampling is performed without any pain relief method. The baby is filmed during a blood draw. The infant pain level will be measured with the NIPS scale during blood sampling and the results of the three groups will be compared.

Participants/Inclusion and exclusion criteria

Infants with 3 to 10 days of age with jaundice are included in the study. Jaundice infants with other disorders that require serum therapy and medication are not included in the study.

Intervention groups

To perform the intervention, a pacifier is used 120 seconds before and during venous blood sampling in the NNS group, and the mother can be present with the baby if she wishes. In the "mother's voice" group, the mother talks to the baby in person from one minute before the end of the blood sampling. In the control group, the baby will be sampled routinely under the care of a nurse.

Main outcome variables

Reduce baby pain during blood sampling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210922052549N1**

Registration date: **2021-10-02, 1400/07/10**

Registration timing: **prospective**

Last update: **2021-10-02, 1400/07/10**

Update count: **0**

Registration date

2021-10-02, 1400/07/10

Registrant information

Name

Maryam Korai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4253 0286

Email address

kordi.maryam1365@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2021-12-31, 1400/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of non-nutritional sucking and maternal voice on venous blood sampling pain in neonates

Public title

Effect of non-nutritional sucking and maternal voice on venous blood sampling pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Infant jaundice
Parents' consent for the baby to participate in the research
Infants with a gestational age of 37 to 42 weeks
Confirmation of the baby's health by a specialist doctor
The baby is healthy in terms of hearing and approved by a specialist doctor
Birth weight 2500 to 3500 grams
Baby age between 3 to 10 days
Calm and awake baby
Do not take Acetaminophen or any other Analgesic the night before
Temperature between 36.5 to 37
No hypoglycemia
Absence of previous painful intervention such as circumcision and serum therapy
Dry baby diapers

Exclusion criteria:

Severe infant restlessness
Maternal dissatisfaction with continuing to participate in the study
Failure to draw blood for the first time
Non-sucking of the infant
Non-talking of the mother

Age

From **3 days** old to **10 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

105 samples of eligible infants whose mothers are willing to participate in the study are selected. The samples are divided into three equal groups by block random method which is done with the help of software. To perform random blocking method, the statistician uses block software to perform block randomization and list the patients with ABC code. Provides the researcher with the samples that meet the inclusion criteria to enter the study in order and using the list provided by the statistician.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Arak University of Medical Sciences, Basij Square

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2021-08-29, 1400/06/07

Ethics committee reference number

IR.ARAKMU.REC.1400.135

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Pain score on the NIPS scale

Timepoint

Measuring the amount of pain during blood sampling

Method of measurement

NIPS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: NNS intervention group that uses Baby Land pacifier made in Iran for the baby.

Category

Other

2

Description

Intervention group: In the mother's voice group, the

baby's mother speaks to the baby in a whispering voice

Category

Other

3

Description

Control group: In the control group, the baby is taken with routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Maryam Kordi

Street address

No.24,Nikfar alley.,Gole sorkhi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Maryam kordi

Position

Student

Latest degree

Bachelor

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 further information

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