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

Nursery

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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