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
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Maryam Korai
Name of organization / entity
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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

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
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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

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

**Recruitment centers**

1

**Recruitment center**

Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
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**Sponsors / Funding sources**

1

**Sponsor**

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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
eempty
Country of origin
Type of organization providing the funding
Academic

**Person responsible for general inquiries**

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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