

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Comparison of the effectiveness of relaxing Voice and Tune voices using voice pillow on pain intensity of heel stick in hospitalized neonates

#### Protocol summary

##### Study aim

1- Determining the mean of heel hemorrhage pain severity in the control group newborns. 2- Determining the mean of heel hemorrhage pain severity in the Voice intervention group newborns. 3- Determining the mean of heel hemorrhage pain severity in Tune intervention group newborns. 4. Make a comparison between the mean of heel hemorrhage pain severity in three groups.

##### Design

This study consists of two groups of intervention (Voice and Tune) and a control group, the initial selection of the samples is available and easy, and randomly (writing groups on the card and random selection of cards) in the target group. Total sample size are: 84 persons.

##### Settings and conduct

Sampling was carried out at the selected from hospitals affiliated to Isfahan University of Medical Sciences (Imam Hossein, Shahid Beheshti and Alzahra) and the sampling was done by the first fellow researcher and researcher during the filming of the neon, and the second collaborator researcher in The sampling stream does not scan videos with the eyes of the baby and blindness is done.

##### Participants/Inclusion and exclusion criteria

Babies admitted to selected hospitals of Isfahan University of Medical Sciences whose gestational age is 34 weeks and older and have a blood glucose check for parasite sampling.

##### Intervention groups

In the intervention group, the baby is sleeping on the pillow made by the researcher, and the song is played by the group and placed in the group for three minutes. In the control group, the baby is sleeping on the pillow and three minutes later, without music playing.

##### Main outcome variables

Severity of pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180526039844N1**

Registration date: **2018-07-03, 1397/04/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-03, 1397/04/12**

Update count: **0**

##### Registration date

2018-07-03, 1397/04/12

##### Registrant information

##### Name

ریعی فرادنبه Manijeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3452 4290

##### Email address

m.rabiey@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-13, 1396/12/22

##### Expected recruitment end date

2018-09-22, 1397/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effectiveness of relaxing Voice and Tune voices using voice pillow on pain intensity of heel stick in hospitalized neonates

**Public title**

Effect of Voice and Tune in pain of neonates

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Baby has a fetal age of 34 weeks and older The need for blood sampling from the heel There is no congenital anomaly in the form of cleft lip and palate The baby is not sleeping and is not crying Do not use a sedative or medication within 24 hours The baby has no hearing problem Failure to receive other painful procedure before intervention

**Exclusion criteria:**

Babies under 34 weeks No need to bleed from the heel There is a hearing problem Congenital malformation of the cleft lip and palate The baby is sleeping or crying Has received a home medicine within the last 24 hours

**Age**

From **238 days** old to **273 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Small cards are made up of the total volume of the sample, and they are written in the Voice group, the Tune intervention and the control group, each with the same number and the size of the sample size in each group. Then the cards are placed inside the box and, during the sampling, according to The card accident crashes out of the box and the newborn is placed in the same group and the cards are picked out of the box. This will continue until the entire card is removed from the box.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Simultaneously, by sampling the changes in the face and limb of the infant, a researcher colleague randomly assigned to the groups is filmed, and the films will be encoded by the first fellow of the researcher without specifying the intervention group or the control group. And the code is behind the card The second collaborator who does not group videos of newborns reviews the videos and evaluates them according to the Nips criteria. Then, the researcher will match the code with the code

behind the cards, which determines which score is for which intervention group, and analyzes the data he is doing it.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In this study, audio pillows are used to play music, which is an innovation aspect and the pillow is designed to not damage the baby's ear, and with a sound level for babies of 35-40 dB that accurately measures this volume.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jerib street, isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2018-02-26, 1396/12/07

**Ethics committee reference number**

IR.MUI.REC.1396.3.823

**Health conditions studied****1****Description of health condition studied**

Pain caused by neonatal blood sampling

**ICD-10 code**

Y84.7

**ICD-10 code description**

Blood-sampling as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

**Primary outcomes****1****Description**

Intensity of pain

**Timepoint**

3 minutes after playing voice or tune, through the pillow and in the control group 3 minutes after pillow sleep.

**Method of measurement**

Neonatal Infants Pain Scale

## Secondary outcomes

### 1

#### Description

Score pain severity

#### Timepoint

3 minutes after the intervention

#### Method of measurement

Neonatal Infant Pain Scale

## Intervention groups

### 1

#### Description

In the first intervention (voice group), the baby is sleeping on an acoustic pillow and a sedative vocal with specific sound intensity (35-40 dB) is distributed to the baby. Then, after 3 minutes, he takes blood from the baby and is filmed by a researcher fellow. The second co-worker examines films for the baby.

#### Category

Treatment - Devices

### 2

#### Description

Intervention group:(tune group): In the second intervention (the tune group), the baby is sleeping on an audio pillow and the sedative with a specific voice intensity (40-35 dB) is distributed to the baby. Then, 3 minutes later, he takes blood from the newborn and infants by the partner The researcher filmed and the second colleague of the researcher scores videos for the baby

#### Category

Treatment - Devices

### 3

#### Description

#### Category

*empty*

### 4

#### Description

Control group:The baby is sleeping on the audio pillow and without any intervention, after 3 minutes, the baby is taken from the infant and the baby is filmed by a researcher's colleague and the second co-worker is evaluating the films for the baby

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Al-zahra hospital

#### Full name of responsible person

Manijeh Rabiei

#### Street address

Sofe blvd., Shahid Keshvari Highway

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174675731

#### Phone

+98 31 3620 2020

#### Fax

+98 31 3669 1510

#### Email

alzahra@mui.ac.ir

#### Web page address

<http://alzahra.mui.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shahnaz Kohan

##### Street address

Esfahan University of Medical Sciences, Hezar Jerib street

##### City

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##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Email

Kohan@nm.mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Manijeh Rabiei

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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mrabiey1356@gmail.com

## Person responsible for scientific inquiries

### Contact

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**Other areas of specialty/work**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

In this study, the score for neonatal pain is given on a neon film. Neonatal films are not shared, but the pain score will be shared in the intervention and control groups

**When the data will become available and for how long**

Get started 6 months after printing results

**To whom data/document is available**

For researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

In order to cite the results of data in research studies

**From where data/document is obtainable**

mrabiey1356@gmail.com

**What processes are involved for a request to access data/document**

The requestor can receive files within two weeks from sending emails through the introduction of his specifications by email and for which purpose he wants

to

**Comments**