Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of music and oral sucrose on vaccination's pain in infants.

Protocol summary

Study aim
Comparing the effect of music and oral sucrose on vaccination's pain in infants.

Design
The clinical trial consisted of two intervention groups, one control group, single -blind and randomized on 135 infants. Children are assigned to groups based on a randomization sequence and first in first out that will be generated in advance, which is unpredictable and has no certain pattern. To assign samples to 3 groups, the block randomization method with the size of 3 and 6 blocks using block random number generator software will be used.

Settings and conduct
This study will be performed in health centers of Khomein city and in infants referred for injection of the Pentavalent vaccine.

Participants/Inclusion and exclusion criteria
Inclusion criteria: awakening of the infant; healthy hearing and eligibility for taking Pentavalent vaccine. exclusion criteria: no history of hospitalization due to illness or surgery; no cold or diarrhea during vaccination; no taking of analgesic for 48 hours before vaccination.

Intervention groups
In the first intervention group (music), the melody of golden dreams by Javad Maroufi will be played from a distance of one meter from three minutes before to three minutes after the injection of the vaccine. The volume will be adjusted by Pazhand Teb Company using the mod-Tes 1354 sound meter made by Tes Taiwan Company at 65 decibels. In the second intervention group (sucrose), one ml of 24% sucrose solution will be given to the infant, after ten seconds, vaccination will be performed. The sucrose powder used in this study is a product of Merck Company.

Main outcome variables
Intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161210031328N12**
Registration date: **2021-02-23, 1399/12/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-23, 1399/12/05**
Update count: **0**

Registration date
2021-02-23, 1399/12/05

Registrant information

Name
Mahbobeh Sajadi

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 86 3402 0115

Email address
m.sajadi@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-20, 1399/09/30

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of music and oral sucrose on vaccination's pain in infants.

Public title
The effect of music and oral sucrose on vaccination's pain.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Awakening of the infant Healthy hearing of the child Having the conditions to receive Pentavalent vaccine
Exclusion criteria:
No history of hospitalization due to illness or surgery No colds or diarrhea during vaccination No taking of Analgesic (painkiller) for 48 hours before vaccination
Age
From **6 months** old to **6 months** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **135**
Randomization (investigator's opinion)
Randomized
Randomization description
Children are assigned to two intervention groups and one control group based on the randomization sequence that will be generated in advance, which is unpredictable and its arrangement is completely random. To allocate the samples, the block randomization method with the size of 3 and 6 blocks will be used, so that by using the software for generating random numbers in the block method, a randomization sequence will be generated according to the sample size required for the three groups. First, all the modes in which the 3 letters A, B and C can be put together in blocks of 3 and 6 are generated, then a block is randomly selected by placing it among the blocks and the layout pattern in that block will be used to allocate children. Finally this block will be placed in the main container and another block will be selected again. Blocks of 3 and 6 will all be in the same container. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.
Blinding (investigator's opinion)
Single blinded
Blinding description
The data analyzer will not know how the samples are placed in the intervention and control groups.
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
Arak University of Medical Sciences, Alam al-Huda St., Railway Square
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2020-11-02, 1399/08/12
Ethics committee reference number
IR.ARAKMU.REC.1399.223

Health conditions studied

1

Description of health condition studied
Vaccination's pain in infants.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intensity of pain
Timepoint
After intervention
Method of measurement
The pain scale used in this study is MBPS (Modified Behavioral Pain Scale).

Secondary outcomes

empty

Intervention groups

1

Description
The first Intervention group: music The melody of golden dreams by Javad Maroufi will be played from a distance of one meter from three minutes before to three minutes after the injection of the vaccine. The volume will be

adjusted by Pazhand Teb Company using the mod-Tes 1354 sound meter made by Tes Taiwan Company at 65 decibels.

Category

Other

2

Description

The second Intervention group: sucrose One ml of sucrose solution 24% will be given to the infant, after ten seconds, vaccination will be performed. The sucrose powder used in this study is a product of Merck Company.

Category

Other

3

Description

Control group: In this group there is no intervention, only vaccination will be performed then the infant's pain intensity will be measured in a appropriate way by modified behavioral pain scale(MBPD).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Khomein city

Full name of responsible person

Mahbobeh Sajadi

Street address

Basij Sq., Sardasht Region, Arak University of Medical Sciences

City

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zeynabbeheshti7941@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

دکتر علیرضا کمالی

Street address

University complex of the Great prophet, Basij square, Sardasht.

City

Arak

Province

Markazi

Postal code

3819693345

Phone

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Email

sajadimahbobeh@yahoo.com

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

80

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

Mahbobeh Sajadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data related to the original outcome will be able to be shared.

When the data will become available and for how long

since the summer of 2021

To whom data/document is available

Researchers and students in this field

Under which criteria data/document could be used

In order to control pain in infants

From where data/document is obtainable

Vice Chancellor for Education and Research, Arak University of Medical Sciences

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

These documents will be available on the website of Arak University of Medical Sciences

Comments