Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Maternal hearing the sound on Non Stress Test(NST) results

Protocol summary

Study aim
Determining the effect of hearing sound on stress test results

Design
The present study will be performed as a control trial with a control group, randomly based on purpose, three-blinds, which will be performed on 106 pregnant women with a gestational age of 32-42 weeks of gestation with inclusion criteria

Settings and conduct
The present study will be conducted in Asali Teaching Hospital, people will be randomly divided into two groups of intervention and control. In the intervention group, after ensuring the health of the auditory canal using a special music headset during the non stress test, which lasts 20 minutes, will be played(It should be noted that the type of music and the degree of sound will be the same in all samples of the intervention group), and in the control group, under the same conditions, normally without playing test music without Stress will be taken.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Auditory canal health, Gestational age 32-32 weeks, Single pregnancy with healthy fetus, No symptoms of childbirth, No smoking, drugs or sedatives and drugs that cause maternal depression./Exclusion criteria: Multiple pregnancy, Maternal fasting, Decreased amniotic fluid volume (oligohydramnios based on ultrasound evidence)

Intervention groups
Listening to music with a headset in the intervention group during the non stress test of fetal heart rate

Main outcome variables
After the end of the Non StressTest (end of 20 minutes), the results of the non stress test included the baseline fetal heart rate, number of fetal movements, number of accelerations,Beat-to-Beat variability, and the time to reach the reactive NST will be checked.Anxiety scores are also determined based on the Spielberger questionnaire. And all the outcomes are compared in the two groups of intervention and control.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200111046079N1**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-01, 1399/06/11**
Update count: **0**

Registration date
2020-09-01, 1399/06/11

Registrant information
Name
Leila Fathi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-21, 1399/05/31
Expected recruitment end date
2020-11-04, 1399/08/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Maternal hearing the sound on Non Stress

Test(NST) results

Public title
The effect of hearing the sound on Non Stress Test(NST) results
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Auditory canal health gestational age 32-32 weeks single pregnancy with healthy fetus no symptoms of childbirth(Uterine contractions and pain, rupture of amniotic membrane, vaginal bleeding, etc.) no smoking, drugs or sedatives and drugs that cause maternal depression
Exclusion criteria:
Maternal fasting Decreased amniotic fluid volume (oligohydramnios based on ultrasound evidence) Any unreliable pattern of fetal heart rate (including Decreased fetal heart rate, bradycardia, tachycardia, etc.)
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was simple with no substitution, so that two cards with numbers one and two, each of which represented the intervention and control group, were given to the first person,She, after selecting one of the cards. She entered the relevant group and the second person was automatically assigned to the opposite group of the previous person and again the cards were presented to the third person for selection and thus continued until the sampling was completed.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, which was performed in three-way blinds, a researcher colleague was used to randomly allocate samples to blind the researcher. After entering the special room for NST, the samples were performed by a fellow researcher to establish the sound of music, and for the control group, a headset device without playing music was placed on the ear of the control group, Therefore, the researcher was not able to distinguish the two groups of intervention and control. Finally, in order to evaluate and interpret the results of the study, which was performed by three people, including the researcher, a gynecologist and a reproductive health specialist, all individuals were unaware of the placement of the samples in the intervention and control groups. The data analyzer, who had the groups as the names of groups 1 and group 2, was unaware of the main nature of groups 1 and 2.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences
Street address
Office of Research Ethics Committee, Vice Chancellor for Research and Technology Lorestan University of Medical Sciences., Pardis University Complex., 3 km of Khorramabad Tehran., Khorramabad Town
City
Khoramabad
Province
Lorestan
Postal code
6813833946
Approval date
2019-02-17, 1397/11/28
Ethics committee reference number
IR.LUMS.REC.1397.178

Health conditions studied

1

Description of health condition studied
Fetal Heart Rate
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fetal heart rate Base Line
Timepoint
20 minutes after the start of the study
Method of measurement
External electronic monitoring device for fetal heart

2

Description
Beat to Beat Variability

Timepoint
20 minutes after the start of the study
Method of measurement
External electronic monitoring device for fetal heart

3

Description
Acceleration number
Timepoint
20 minutes after the start of the study
Method of measurement
External electronic monitoring device for fetal heart

4

Description
Test response time
Timepoint
20 minutes after the start of the study
Method of measurement
External electronic monitoring device for fetal heart

5

Description
Fetal Movement
Timepoint
20 minutes after the start of the study
Method of measurement
External electronic monitoring device for fetal heart

6

Description
Anxiety
Timepoint
20 minutes after the start of the study
Method of measurement
Spielberger Questionnaire

Secondary outcomes

1

Description
Time required to respond to the Non Stress Test
Timepoint
Every minute until the end of twenty minutes
Method of measurement
External electronic monitoring device for fetal heart

Intervention groups

1

Description
Intervention group: In the intervention group, pregnant women are routinely connected to an external fetal heart rate monitor to perform a Non Stress Test(NST) to assess the health of the fetus, and then a music player headset will be placed on the ear by the researcher assistance. And pregnant women will listen to non-verbal music throughout the 20-minute Non Stress Test(NST). It should be noted that the type of music and sound level will be the same in all members of the intervention group.
Category
Other

2

Description
Control group: In this group, pregnant women are connected to the external fetal heart rate monitoring device to perform a Non Stress Test(NST) to assess the health of the fetus, and then the music player headset is turned off and only to blind the researcher and Observing the same conditions in both groups with the help of the researcher assistance be placed on people's ears during 20 minutes of Non Stress Test(NST)
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Asali Teaching Hospital
Full name of responsible person
Leila Fathi
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koy palestin, shariati str, Khorramabad Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Ebrahim Falahi
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Vice Chancellor for Research and Technology, University of Medical Sciences Campus Complex, 3 km Khorramabad-Boroujerd, Khorramabad city, Lorestan province
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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
Khoram-Abad 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Leila Fathi

Position
Faculty instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All research results and data will be provided to Asali

Educational Center and University

When the data will become available and for how long

In this plan, it is possible to access the results Six month after the final analysis of the data and the final report to the University of Medical Sciences

To whom data/document is available

Vice Chancellor for Research and Technology of the University, Asali Teaching Hospital, which is the place of research, and also those involved in the medical equipment industry to use the research results to upgrade the external fetal heart monitoring device.

Under which criteria data/document could be used

To help invent and upgrade external fetal heart rate monitors

From where data/document is obtainable

To use the data, applicants can contact Ms. Leila Fathi, faculty member of Lorestan University of Medical Sciences, at 09163677217, and email address MID_FATHI@YAHOO.COM, Khorramabad, 3 km from Khorramabad Road, Tehran, University campus complex to apply

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

The applicant will be able to receive the results after obtaining the necessary permits from Lorestan University of Medical Sciences and after the approval of the Vice Chancellor for Research and Technology of the relevant university

Comments