Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparison of two methods of music listening, by mother and fetus on the non-stress test outcome in pregnant women referring to Hafez and Zeinabie hospital of Medical Sciences University of Shiraz 2011.

Protocol summary

Summary

Objective: The aim of this study was comparison two methods of music listening by mother and fetus on non-stress test outcome. Study design: single blind clinical trial Participant selection: Inclusion criteria: gestational age 37- 40 weeks of pregnancy; singleton pregnancy; Women with uncomplicated pregnancies; no chronic disease in mother; not strenuous physical activity until two hours before the test; no use of analgesics, narcotics, sedative and effected drugs on uterine contractions; Before entering the study vibroacoustic stimulation, glucose or fruit juice is not used; at least 1.5 is the last time the mere promise of a meal; no nonreactive non-stress test; Exclusion criteria: any problem occurred during the study; not wanting to continue more; more than three positive non-stress test. sample size: 213 Patients are randomly assigned to three 71 member groups including a control and two intervention groups. In the mother intervention group, at the beginning of the second 10 minutes of test the classical music is played. In the Fetal intervention group, also, at the beginning of the second 10 minutes the classical music is played for 15 seconds with three notes trigger and a maximum amplitude of 95 dB, played on the mothers' belly and the vertex of the fetus. Then the intervention times of these groups and, also, times before and after intervention in each group were compared. primary outcome : Using Music for mother and fetus will increase acceleration and reduces false-positive results in non-stress test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112108362N1**

Registration date: **2013-01-21, 1391/11/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-21, 1391/11/02

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Shiraz University of Medicine Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of two methods of music listening, by mother and fetus on the non-stress test outcome in

pregnant women referring to Hafez and Zeinabie hospital of Medical Sciences University of Shiraz 2011.

Public title
The comparison of two methods of music listening, by mother and fetus on the non-stress test outcome.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: age range 35-18 years; gestational age 37- 40 weeks of pregnancy; singleton pregnancy; Women with uncomplicated pregnancies include: hypertension disorders, diabetic women requiring insulin, women suspected fetal inter uterine growth restricted, Women after 41 gestational age determinate by last menstruation date or ultrasound 16 to 20 weeks, premature rupture of membranes, multiple pregnancies, intrauterine death fetus, the embryonic lethal anomalies, fetus by cardiovascular anomalies, amniotic fluid disorders, the fetus was diagnosed with anencephaly; baseline of heart rate between 160-110; No pregnant women by loss- hearing; no anatomic or mental disorders in mother (psychosis, schizophrenia, and uterine abnormalities); no chronic disease in mother such as heart disease, lung, kidney, chronic hypertension and diabetes; Not smoking and tobacco; not strenuous physical activity until two hours before the test; no use of analgesics, narcotics, sedative and effected drugs on uterine contractions; Before entering the study vibroacoustic stimulation, glucose or fruit juice is not used; at least 1.5 is the last time the mere promise of a meal; no nonreactive non-stress test; no experience in music education; The written consent form. Exclusion criteria: any problem occurred during the study, including placenta abruption, and cord prolapsed; not wanting to continue more; more than three positive non-stress test (non-reactive); presence of uterine contractions.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **213**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
below Namazi Hospital, Zand Avenue
City
Shiraz
Postal code
Approval date
2011-11-11, 1390/08/20
Ethics committee reference number
90-5813-CT

Health conditions studied

1

Description of health condition studied
Nonstress testing in pregnant women
ICD-10 code
w43
ICD-10 code description
expesure to the vibration

Primary outcomes

1

Description
The number of acceleration of fetal heart rate.
Timepoint
Initial 10 minuts of test, second 10 minuts of test.
Method of measurement
Toito Japanese model by fetal echocardiography

Secondary outcomes

1

Description
Reduce of time of nonstress testing
Timepoint
Initial 10 minuts of test, second 10 minuts of test.
Method of measurement
Toito Japanese model by fetal echocardiography

Intervention groups

1

Description
Music intervention in group1 by the mother and music run during the second 10 minutes of nonstress test .and

during of test not eating juice by mother or working for reduce mother,s stress.

Category

Treatment - Devices

2

Description

Group 2, intervention of music listening by fetus from mother.s abdominal wall since 15 second after lost of 10 minute of non-stress testing. and during of test not eating juice by mother or working for reduce mother,s stress.

Category

Treatment - Devices

3

Description

Third group is control.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez and Zienabiye Hospital, Shiraz

Full name of responsible person

Keshavarz Tahereh.

Street address

School of Nursing and Midwifery, Namazi Square Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Shiraz University of Medical Sciences

Full name of responsible person

Dr Skandari

Street address

Namazi Hospital, , Zand Avenue

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Roghayeh Khoshkholgh

Position

Bachelor of midwifery

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty