Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of caffeine consumption and voice stimulation before biophysical profiling on the biophysical profile of fetal profile in pregnant women with single pregnancy

Protocol summary

Study aim
The effect of taking caffeine by the mother before performing biophysical profiles on embryonic biophysical profile

Design
Clinical trial with control and intervention group, with parallel groups, Not blind, randomized ,Sample size 150 people

Settings and conduct
This study will be conducted on 150 patients referring to Tabriz Al-Zahra Health Center. They will be randomly divided into 3 groups of 50 people. Control group: group (control) received no intervention. The intervention group A: 20 grams of instant coffee powder, made in France, containing 120 mg of caffeine, dissolved in 200 cc of boiling water and drank before the procedure. Intervention group Two: The acoustic stimulus recipient will be hit by the metal rod next to the patient's bed, before the procedure, using a reflex hammer.

Participants/Inclusion and exclusion criteria
Pregnant mothers are candidates for a biophysical test for embryonic profiles that are willing to participate in the study and will not be included in the study if they have a mental illness or bleeding and pain.

Intervention groups
Control group: group (control) received no intervention. The intervention group A: 20 grams of instant coffee powder, made in France, containing 120 mg of caffeine, dissolved in 200 cc of boiling water and drank before the procedure. Intervention group Two: The acoustic stimulus recipient will be hit by the metal rod next to the patient's bed, before the procedure, using a reflex hammer.

Main outcome variables
Amount of time needed to complete the biophysical profile and Biophysical Profiles Scours

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190304042912N2**
Registration date: **2019-07-28, 1398/05/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-28, 1398/05/06**
Update count: **0**

Registration date
2019-07-28, 1398/05/06

Registrant information

Name
sanaz moosavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3553 9161

Email address
musevis@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-24, 1398/05/02

Expected recruitment end date
2020-07-23, 1399/05/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of caffeine consumption and voice stimulation before biophysical profiling on the biophysical profile of fetal profile in pregnant women with single pregnancy

Public title
The effect of taking caffeine by the mother before performing biophysical profile on fetal biophysical profile

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
En Pregnant mothers are candidates for a biophysical test for embryonic profiles Having the consent to participate in the study
Exclusion criteria:
have a mental illness bleeding pain

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were divided randomly into three groups of 50: group I (control) received no intervention; group II (caffeine-recipient) took caffeine before the procedure; and group III (acoustic stimulation) received acoustic stimulation before the procedure using a reflex hammer.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Tabriz University Of Medical Sciences
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471

Approval date
2019-04-08, 1398/01/19

Ethics committee reference number
IR.TBZMED.REC.1398.031

Health conditions studied

1

Description of health condition studied
Evaluating the health of the fetus

ICD-10 code
P00

ICD-10 code description
Fetus and newborn affected by maternal conditions that may be unrelated to present pregnancy

Primary outcomes

1

Description
Amount of time needed to complete the biophysical profile

Timepoint
the time elapsed to begining of fetal heart rate reactivity

Method of measurement
ultrasound timer

2

Description
Score biophysical profile(Fetal breathing movements, fetal movements, fetal tone, fetal heart rate, speed, volume of amniotic fluid)

Timepoint
Pre-intervention and post-intervention

Method of measurement
Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Control group: No intervention will be received.

Category
N/A

2

Description
The intervention group A: 20 grams of instant coffee powder, made in France, containing 120 mg of caffeine,

dissolved in 200 cc of boiling water and drank before the procedure.

Category

Diagnosis

3

Description

Intervention group Two: The acoustic stimulus recipient will be hit by the metal rod next to the patient's bed, before the procedure, using a reflex hammer.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Sanaz Musavi

Street address

Alzahra Hospital, South Artesh St.

City

Tabriz

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East Azarbaijan

Postal code

5138665793

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+98 41 3553 9161

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lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Juiban

Street address

Third Floor, Central Building of Number2, Golgasht Street

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Sanaz Musavi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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