

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 beginning 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

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3553 9161

Email

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

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3553 9161

Email

lahroudin@gmail.com

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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Tabriz University Of Medical Sciences, Golgasht Street

City

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Postal code

5138665793

Phone

+98 41 3553 9161

Email

lahroudin@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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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