

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of listening to the Quran on the level of cortisol in pregnant women undergoing cesarean section a clinical trial study

Protocol summary

Summary

The main objectives of the study: The effect of listening to the Quran on the level of cortisol changes in pregnant women undergoing cesarean section. The effect of listening to the Quran on level of systolic and diastolic blood pressure and heart rate in pregnant women undergoing cesarean section. Study Design: clinical trial without placebo. This study was done on 60 pregnant women (30 intervention and 30 control). Sample selection is done by simple randomization. This study is done in a teaching hospital. Blinding is not done. This study is a Phase 2 clinical trial. In the intervention group, vital signs are recorded, blood samples were taken to measure plasma cortisol. Then, pregnant women listen to Quran. After spinal anesthesia, vital signs are recorded and blood sample of umbilical cord is taken for measuring plasma cortisol level. In the control group, all the steps are done except listening to Quran. Inclusion criteria: primigravid pregnant women; 20 to 35 years old; gestational age 37-40 weeks; candidate for elective cesarean section; Muslims; An uncomplicated pregnancy, Singleton pregnancy exclusion criteria: increasing the duration of cesarean (more than one hour); patient does not tolerate headphone; takes any sedative drug during anesthesia. The main outcome variable: cortisol changes. Secondary outcomes: systolic blood pressure, diastolic blood pressure, heart rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601126243N2**

Registration date: **2016-03-09, 1394/12/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-09, 1394/12/19

Registrant information

Name

Shiva Rafati

Name of organization / entity

Shahed university

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 9437

Email address

rafati@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahed University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of listening to the Quran on the level of cortisol in pregnant women undergoing cesarean section a clinical trial study

Public title

Effects of Quran on pregnant mothers, stress

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: primigravid pregnant women;20 to 35 years old; gestational age 37-40 weeks;candidate for elective cesarean section;Muslims; An uncomplicated pregnancy, Singleton pregnancy exclusion criteria :increasing the duration of cesarean (more than one hour); The patient does not tolerate head phone ; takes any sedative drug

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

simple randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University of Medical Sciences

Street address

Shahed university,in front of holy shrine of Imam Khomeni, the Persian Gulf highway

City

Tehran

Postal code

Approval date

2013-12-10, 1392/09/19

Ethics committee reference number

IR.shahed.REC.1392.29

Health conditions studied

1

Description of health condition studied

XV Pregnancy, childbirth and the puerperium

ICD-10 code

(O00-O99)

ICD-10 code description

pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

cortisol

Timepoint

before intervention and one hour after intervention

Method of measurement

blood sampling

Secondary outcomes

1

Description

diastolic blood pressure

Timepoint

before intervention and 30 minutes after intervention

Method of measurement

Sphygmomanometer , millimeter Hg

2

Description

systolic blood pressure

Timepoint

before intervention and 30 minutes after intervention

Method of measurement

Sphygmomanometer , millimeter Hg

3

Description

heart rate

Timepoint

before and 30 minutes after intervention

Method of measurement

heart rate monitoring device

Intervention groups

1

Description

intervention group:listening to Quran during 20 minutes

Category

Other

2

Description

control group :no intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mustafa Khomeini Hospital

Full name of responsible person

Shiva Rafati

Street address

Italia street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, shahed University of Medical Sciences

Full name of responsible person

Dr kiasalari

Street address

persian Gulf highway,in front of Holy shrine of Imam Khomeini

City

Tehran

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, shahed 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

general practitioner, Graduated from Shahed university of medical science

Full name of responsible person

zahra abdoolah poor

Position

Shahed university of medical science

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed university of medical science

Full name of responsible person

Shiva rafati

Position

assistant professor

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Position

assistant professor

Other areas of specialty/work

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Web page address

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