

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Khomeini, 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

Tehran  
**Postal code**  
**Phone**  
+98 21 8896 4792  
**Fax**  
**Email**  
Medicine@shahed.ac.ir  
**Web page address**

**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**  
**Street address**  
Shahid Baradaran Abdollah Zade street,Boulvar  
Keshavarz  
**City**

**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  
**Other areas of specialty/work**  
**Street address**  
Shahid Baradaran Abdollah zade,Boulvar keshavarz  
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medicine@shahed.ac.ir  
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**Person responsible for updating data**

**Contact**

**Name of organization / entity**  
Shahed university of medical science  
**Full name of responsible person**  
shiva rafati  
**Position**  
assistant professor  
**Other areas of specialty/work**  
**Street address**  
Shahid Baradaran Abdollah zade street , Boulvar  
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**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 8896 9437  
**Fax**  
**Email**  
medicinei@shahed.ac.ir  
**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*