

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Study of the Effects of relaxation therapy in reducing anxiety in patients referred for elective cesarean

#### Protocol summary

##### Study aim

A convenient way to reduce the anxiety caused by elective cesarean section

##### Design

This community-oriented and pragmatic control group was conducted with parallel, randomized, and blinded groups. Each group included 45 people.

##### Settings and conduct

Interventions will be done once per hour and in total four times until the time of surgery for pregnant women. For the control group, a neutral item (fruit and vegetable properties) provided and presented to them. The access to the patients in person will be in the ward of obstetrics and gynecology in Ahwaz Imam Khomeini Hospital. After collecting data based on the Hamilton anxiety scale in both control and intervention groups, the results will be analyzed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All pregnant women who are referred for elective cesarean section  
Exclusion criteria: History of continuous use of benzodiazepines, antipsychotics, psychotropic drugs and opiates.

##### Intervention groups

After assessing the concerns, the amount of patient information and beliefs about performing cesarean section will take place in three areas of cognitive and behavioral information intervention. The duration of the intervention for the intervention group will be performed in the control group for progressive muscle relaxation for 20-25 minutes.

##### Main outcome variables

Mental anxiety; physical anxiety; radial pulse; number of respiration.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150121020739N5**

Registration date: **2018-03-24, 1397/01/04**

Registration timing: **retrospective**

Last update: **2018-03-24, 1397/01/04**

Update count: **0**

##### Registration date

2018-03-24, 1397/01/04

##### Registrant information

###### Name

Forouzan Behroozina

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3374 3038

###### Email address

behrouzian-f@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

2016-05-21, 1395/03/01

##### Actual recruitment end date

2017-06-22, 1396/04/01

##### Trial completion date

empty

##### Scientific title

Study of the Effects of relaxation therapy in reducing anxiety in patients referred for elective cesarean

##### Public title

Effects of relaxation therapy in reducing anxiety in patients referred for elective cesarean

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

All pregnant women who are referred for elective cesarean section Have at least written literacy Examination and ultrasonographic examination of the pelvis and normal tests include prolactin in the range of 4-23 ng / ml, TSH in the range of 0.3-5 U / ml and FSH in the range 4.7-21.5 mIU / ml

### Exclusion criteria:

History of continuous use of benzodiazepines, antipsychotics, psychotropic drugs and opiates. History of anxiety disorders and attacks, or any history of previous psychiatric illness The presence of dystocia and hard labor in previous pregnancies Early baby birth in previous pregnancies any maternal and perinatal risk of cesarean delivery as non-active. Smoking or history of drug use and anti-anxiety History of congestive heart disease-asthma-COPD-type 1 and type 2 diabetes, history of hypertension

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **26**

Actual sample size reached: **26**

## Randomization (investigator's opinion)

Randomized

## Randomization description

randomization was done by random number table

## 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 Ahvaz Jundishapur University of Medical Sciences

##### Street address

Azadegan Ave, Imam khomeini Hospital

##### City

Ahvaz

## Province

Khouzestan

## Postal code

6135715794

## Approval date

2017-04-17, 1396/01/28

## Ethics committee reference number

IR.AJUMS.REC.1396.735

## Health conditions studied

### 1

#### Description of health condition studied

anxiety

#### ICD-10 code

F40,F41,F4

#### ICD-10 code description

Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

Comparison of anxiety level in intervention and control group

#### Timepoint

before and after cesarean section

#### Method of measurement

Hamilton Anxiety Inventory

### 2

#### Description

Determining the Relationship between Clinical Factors and the Impact of Mental Readiness

#### Timepoint

before and after cesarean section

#### Method of measurement

Hamilton Anxiety Inventory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After assessing the concerns, the patient's information and beliefs about cesarean delivery in three areas of cognitive and behavioral information will be subjected to the following intervention: 1.

Information control: At this stage, the patient's incorrect information is corrected and additional information on how to perform it. Caesarean section, time, duration, and general conditions for conducting cesarean section will be given to the patient. 2. Cognitive control: Due to the cognitive distortions in the patient, cognitive control will

be provided to the patient (for example, the patient's attention to the benefits of the operation And its positive points instead of emphasizing the unpleasant and negative aspects of it) 3- Behavioral control: from the face Behavioral control items including specific respiratory exercises, relaxation, distraction technique, etc. will be provided to the patient to use these methods in case of anxiety.

**Category**

Behavior

**2****Description**

Control group: The duration of the intervention is for the case group. In the case group, progressive muscle relaxation will be performed for 25-20 minutes

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam khomeini Hospital

**Full name of responsible person**

Horasa Tabibi

**Street address**

Azadegan Ave. Imam khomeini Hospital

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 3374 3038

**Email**

Horasa\_tabibi@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Horasa Tabibi

**Street address**

Ahvaz Jundishapur University of Medical Science,  
Golestan Blvd

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 3374 3038

**Email**

Horasa\_tabibi@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Horasa Tabibi

**Position**

professional doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Imam Khomeini Hospital, Azadegan Ave.

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 3374 3038

**Email**

Horasa\_tabibi@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Horasa Tabibi

**Position**

professional doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Imam khomeini Hospital, Azadegan Ave.

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 3374 3038

**Email**

horasa\_tabibi@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Horasa Tabibi

**Position**

professional doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Imam Khomeini Hospital, Azadegan Ave.

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 3374 3038

**Email**

Horasa\_tabibi@yahoo.com

**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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable