

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

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

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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

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

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable