

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Assessment the effect of face to face education followed by pamphlet on preoperative anxiety level of pregnant women undergoing elective cesarean section in Shariati hospital.

Protocol summary

Summary

The main purpose: Assessment the effect of face to face education followed by pamphlet about the process of operation and anesthesia on preoperative anxiety level of pregnant women undergoing elective cesarean section. Main inclusion criteria: No having experience of any surgery; The case of gravid 1 (first cesarean section); ASA class I or II Main exclusion criteria: Level of education below the high school. The design of this study: randomized, single-blind, distribution of STAI(State-Trait Anxiety Inventory) questionnaire and VAS(visual analog scale) scoring tool to both control and intervention groups in a day before cesarean section then face to face education followed by pamphlet to the intervention group and giving STAI questionnaire and VAS scoring tool only to the intervention group after education on the same day. Population of this study: Pregnant women undergoing cesarean section in Dr.Ali Shariati Hospital of Tehran. Sample size: 25 cases in the control group and 25 cases in the intervention group. The intervention in this study: Face to face education followed by pamphlet. Time of the intervention: 2015. Sample size: 25 cases in the control group and 25 cases in the intervention group. Primary outcomes: Anxiety, Type of Anesthesia technique

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060622576N1**
Registration date: **2015-08-09, 1394/05/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-09, 1394/05/18

Registrant information

Name

Alireza Saliminia

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-08-06, 1394/05/15

Expected recruitment end date

2015-09-01, 1394/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of face to face education followed by pamphlet on preoperative anxiety level of pregnant women undergoing elective cesarean section in Shariati hospital.

Public title

The effect of education on anxiety level before cesarean section

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria in both control and intervention groups: No having experience of any surgery;The case of gravid 1 (first cesarean section); ASA class I or II Exclusion criteria in both control and intervention group: Level of education below the high school

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poorsina Street, Keshavarz Avenue, Tehran

City

Tehran

Postal code

1411713135

Approval date

2015-08-01, 1394/05/10

Ethics committee reference number

IR.TUMS.REC.1394.498

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety

Timepoint

before and after the intervention on the same day of intervention in a day before operation

Method of measurement

STAI questionnaire and VAS

2

Description

Type of Anaesthesia technique

Timepoint

After the intervention on a day after cesarean section

Method of measurement

patient file

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

after cesarean section

Method of measurement

asking the patients

Intervention groups

1

Description

One face to face training session followed by Pamphlet in a day before cesarean section to the intervention group

Category

Other

2

Description

without any intervention in control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr.Alireza Saliminia

Street address

Shariati Hospital, Jalal Ale Ahmad Ave, North Karegar St, Tehran, Iran

City

Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

Dr.Shahin Akhoondzadeh

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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

Tehran 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**

Shariati Hospital

Full name of responsible person

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Position

Assistant Professor of Anaesthesiology

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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

