Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 questionnare 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

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Shariati Hospital, Jalal Ale Ahmad Ave, North Karegar St, Tehran, Iran
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Sponsors / Funding sources

1

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

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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*