

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of "nurse companionship" program on health outcomes of mothers undergoing cesarean section

Protocol summary

Summary

this study will be carried out with the aim of identifying the effect of "Nurse Companionship" plan on health outcomes in mothers who are candidate for cesarean section. To achieve specific aims, the anxiety level 1 hour before and 1 hour after the surgery, level of satisfaction 1 hour after surgery, pain severity and vital signs 1 hour before surgery, when the mother is placed on surgery bed and 1 hour after surgery will be measured in both groups. The present study is a clinical trial which will be carried out in Tabriz Alzahra Teaching Hospital after getting permission from research vice chancellor and ethics committee. To do the study the mothers, who are candidate for cesarean section, will be selected randomly considering inclusion criteria. Afterwards, they will be appointed to either intervention or control group. Control group will receive the routine care. The intervention group will get nurse support and companionship before the surgery starts until the end of the surgery. The nurse will start process of supporting by introducing herself to the mothers in control group and elaborating on the study aims, taking mothers' hand in her hand, having eye contact, educating them what they need, answering their question and diverting their attention. It will be also explained to the mothers that the nurse will be with them during the surgery and will answer all their questions if possible. The anxiety level will be measured using Spielberger anxiety questionnaire, the pain level using visual analogue scale (VAS), level of satisfaction using Tabbi patient's satisfaction questionnaire and vital signs values using digital blood pressure monitor ALPK. The collected data will be analyzed.

General information

Acronym

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IRCT registration information

IRCT registration number: **IRCT2016081727561N3**

Registration date: **2016-12-09, 1395/09/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

Name

Mojgan Lotfi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 6770

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of "nurse companionship" program on health outcomes of mothers undergoing cesarean section

Public title

Clinical trial program "nurse companionship" on health outcomes of mothers undergoing cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Candidate for cesarean, Mothers with Non-emergency cases! No nulliparous mothers! Mothers consciousness enough to cooperate! Effective communication between mothers and nurses! No maternal history of allergy to spinal anesthesia! No high risk situation for the baby! Single and term pregnancy. Exclusion Criteria: Unsuccessful spinal anesthesia, Receive general anesthesia! Need another surgery (Hysterectomy)! History of taking Anti-anxiety drugs! Suffering from any mental problems! History of Kidney disease, Cardiovascular disease, Hearing problem and etc.! History of Gestational diabetes, Preeclampsia, Polyhydramnios and etc! History of HIV And Hepatitis! Any thing out of the surgeries routines occur in surgery! Want to exit the study.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 128

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Blocking method

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street

City

Tabriz

Postal code**Approval date**

2016-09-26, 1395/07/05

Ethics committee reference number

IR.TBZMED.REC.1395.682

Health conditions studied**1****Description of health condition studied**

Health outcomes of mothers candidate for cesarean section

ICD-10 code

Z71.9

ICD-10 code description

Counselling, unspecified

Primary outcomes**1****Description**

Anxiety

Timepoint

1 hour before and 1 hour after the surgery

Method of measurement

Spielberger anxiety questionnaire

2**Description**

Pain

Timepoint

1 Hour before surgery, when the mother is placed on surgery bed and 1 hour after surgery

Method of measurement

Visual analogue scale (VAS)

3**Description**

Vital sign

Timepoint

1 Hour before surgery, when the mother is placed on surgery bed and 1 hour after surgery

Method of measurement

Digital blood pressure monitor ALPK

Secondary outcomes**1****Description**

Satisfaction

Timepoint

1 Hour after surgery

Method of measurement

Tabbi patient's satisfaction questionnaire

Intervention groups

1

Description

Control group: This routine care includes: accepted the mother in the unit, preparing file, check out routine tests of cesarean section, wear of surgery gun, notice and transfer to the operating room, transfer the mother to the waiting room and then operating table, induction of spinal anesthesia, surgery begins, transfer the mother to recovery after surgery, the recovery and after the return of legs anesthesia transfer the mother to the unit. It should be noted that all the above tasks done by staff the center and without the presence of a researcher.

Category

N/A

2

Description

Intervention group: Mother candidate for cesarean in addition to receive routine care, will get nurse support and companionship 1 hour before the surgery starts until the 1 hour after the surgery. The nurse will start process of supporting by introducing herself to the mothers and elaborating on the study aims, taking mothers' hand in her hand, having eye contact, educating them what they need, answering their question and diverting their attention. It will be also explained to the mothers that the nurse will be with them during the surgery and will answer all their questions if possible.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching Hospital

Full name of responsible person

Elmira Aghaii

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidian

Street address

Daneshgah Street

City

Tabriz

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, Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Elnaz Asghari

Position

Candidate for Ph.D Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Mojgan Lotfi

Position

Assistant Professor

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Person responsible for updating data

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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