

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

A comparative study of hemodynamic effects of manual tilting of the uterus to left during cesarean section under spinal anesthesia

Protocol summary

Study aim

Study of manual left uterus tilting role in preventing the hypotension during elective cesarean section under spinal anesthesia

Design

A randomized clinical trial with parallel groups , with blinded outcome assessment, sample size 70 persons.

Settings and conduct

This study takes place in the Yas hospital. Research information will be recorded in the questionnaire. Finally, the data will be gathered through patients' files and questionnaires and will be analyzed by SPSS software with blinded outcome assessment (The analyst does not know which group is the intervention group and which is the control group).

Participants/Inclusion and exclusion criteria

inclusion criteria: women, elective cesarean section, aged 18 to 40 years exclusion criteria: multiple pregnancy,placental abnormalities,uncontrolled underlying disease

Intervention groups

In the intervention group, right after spinal anesthesia with 2.5 Bupivacaine 0.5% and supine position, in the sterile setting the top border of uterus will deviate to left by anesthesiologist hand staying right side of the patient until infant and placenta will be delivered. The mother's blood pressure and heart rate will be measured and recorded in certain moments also patient's nausea and surgeon satisfaction will be noted. in the control group all steps will be done except uterus deviation.

Main outcome variables

Mother's systolic and diastolic blood pressure ; mother's heart rate; amount of mother's nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190130042559N1**

Registration date: **2020-05-29, 1399/03/09**

Registration timing: **retrospective**

Last update: **2020-05-29, 1399/03/09**

Update count: **0**

Registration date

2020-05-29, 1399/03/09

Registrant information

Name

Mina Amirmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7757 4159

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of hemodynamic effects of manual tilting of the uterus to left during cesarean section under spinal anesthesia

Public title

Effect of manual tilting of the uterus in cesarean section

IR.TUMS.MEDICINE.REC.1397.358

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

women elective cesarean aged 18 to 40 years

Exclusion criteria:

multiple pregnancy placental abnormalities uncontrolled underlying disease

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In a simple random sampling, 70 patients are selected. A number of 70 papers are prepared. The word "intervention" is written on half of the papers and the word "control" is written on the other half. The papers are placed in envelopes and are sealed. Each patient picks up an envelope and is assigned to the intervention or control group based on the paper in the envelope.

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 Tehran University of Medical Sciences

Street address

Building no.1, Northern gate of the university,
Poursina St. Qods St. Enqelab St

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-08-26, 1397/06/04

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Hypotension during cesarean section under spinal anesthesia

ICD-10 code

I95.81

ICD-10 code description

Postprocedural hypotension

Primary outcomes

1

Description

mother's Blood pressure during cesarean section

Timepoint

Mother's systolic and diastolic blood pressure in the following moments: before injection of spinal anesthetic, after injection of spinal anesthetic, before incision of the abdomen, before incision of the uterus, after delivery

Method of measurement

manometer

2

Description

mother's heart rate during cesarean section

Timepoint

mother's heart rate blood pressure in the following moments: before injection of spinal anesthetic, before starting the surgery, before the uterus incision, after delivery

Method of measurement

heart monitor

3

Description

amount of mother's nausea during surgery

Timepoint

once during the surgery

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

newborn's APGAR scale

Timepoint

the 3rd and 5th minute after delivery of the baby

Method of measurement

APGAR scale

Intervention groups

1

Description

Intervention group: the group that receives manual left tilting of the uterus, anesthesiologist stands on the right side of the patients and presses the highest border of the uterus to the left during the surgery until fetus delivery. maternal blood pressure and pulse rate will monitor continuously and register 5 times.

Category

Prevention

2

Description

Control group: the group that goes through the conventional cesarean section without tilting of the uterus. In this group we won't do any intervention on the uterus during cesarean section and only record vital signs.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Ehsan Bastan Hagh

Street address

Yas Hospital, North Nejatollahi St, Kharim Khan Ave

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad-Ali Sahraian

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6th floor, main university building, next to Qods st, keshavarz blvd

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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

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

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Bastan-Hagh

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available