

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparative evaluation between two methods of maintenance of anesthesia : Inhalational anesthesia and Propofol anesthesia on average blood loss and vital sign changes during cesarean delivery in patients with placenta invasion

Protocol summary

Study aim

Comparison between two methods of maintenance of anesthesia : Inhalational anesthesia and Propofol anesthesia on average blood loss and vital sign changes during cesarean delivery in patients with placenta invasion

Design

Two arm parallel group randomised clinical trial with blinded patients and data analyzer.

Settings and conduct

This study will be performed in the years 2020_2021 on patients with placental adhesion who are candidates for cesarean section in the hospitals of Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with placenta invasion Candidate for cesarean section in hospitals of Isfahan University of Medical Sciences No contraindication for general anesthesia Written informed consent Exclusion criteria: Confirmed coagulation disorder Confirmed cardiac disorder Percreta placental adhesion if diagnosed before surgery Egg allergy Recent anesthesia with inhaled anesthetics

Intervention groups

Inhalational anesthesia and Propofol anesthesia

Main outcome variables

Blood loss volume; Units of transfused blood products; Heart rate; Systolic blood pressure; Diastolic blood pressure; Mean arterial blood pressure; Respiratory rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110213005825N3**

Registration date: **2020-12-09, 1399/09/19**

Registration timing: **prospective**

Last update: **2020-12-09, 1399/09/19**

Update count: **0**

Registration date

2020-12-09, 1399/09/19

Registrant information

Name

Parvin Sajedi

Name of organization / entity

Anesthesiology and Critical Care Research Center, Isfahan University of Medical Sciences, Isfahan, I

Country

Iran (Islamic Republic of)

Phone

+98 31 1776 9721

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation between two methods of

maintenance of anesthesia : Inhalational anesthesia and Propofol anesthesia on average blood loss and vital sign changes during cesarean delivery in patients with placenta invasion

Public title

Comparative evaluation between two methods of maintenance of anesthesia : Inhalational anesthesia and Propofol anesthesia on average blood loss and vital sign changes during cesarean delivery in patients with placenta invasion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with placenta invasion Candidate for cesarean section in hospitals of Isfahan University of Medical Sciences No contraindication for general anesthesia Written informed consent

Exclusion criteria:

Confirmed coagulation disorder Confirmed cardiac disorder Percreta placental adhesion if diagnosed before surgery Egg allergy Recent anesthesia with inhaled anesthetics

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 76

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomized / Personal / SPSS statistical software / Random Allocation 38 people are selected for each of the two groups and participants are assigned by SPSS software and random allocation between the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind: patient and data Analyzer

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-11-13, 1399/08/23

Ethics committee reference number

IR.MUI.MED.REC.1399.711

Health conditions studied

1

Description of health condition studied

Placenta invasion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood loss volume

Timepoint

After cesarean section

Method of measurement

Total volume of suction and gases used

2

Description

Units of transfused blood products

Timepoint

After cesarean section

Method of measurement

Patient file

3

Description

Heart rate

Timepoint

Every 15 minutes from the beginning of anesthesia until discharging from recovery

Method of measurement

Monitoring system

4

Description

Systolic blood pressure

Timepoint

Every 15 minutes from the beginning of anesthesia until

discharging from recovery

Method of measurement

Monitoring system

5

Description

Diastolic blood pressure

Timepoint

Every 15 minutes from the beginning of anesthesia until discharging from recovery

Method of measurement

Monitoring system

6

Description

Mean arterial blood pressure

Timepoint

Every 15 minutes from the beginning of anesthesia until discharging from recovery

Method of measurement

Calculation

7

Description

Respiratory rate

Timepoint

Every 15 minutes from the beginning of anesthesia until discharging from recovery

Method of measurement

Monitoring system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Propofol anesthesia. In this group, patients are anesthetized with propofol, the induction dose is 2 mg / kg by bolus injection and the maintenance dose is 0.1 to 0.2 mg / kg by infusion.

Category

Treatment - Drugs

2

Description

Control group: Inhalational anesthesia. In this group, patients are anesthetized with isoflurane. Anesthesia is induced with sodium thiopental and maintenance is performed by 1.2 MAC isoflurane by infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Arman Emami

Street address

Alzahra hospital, soffe Blvd, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh haghjoo

Street address

Hezar Jerib street, Isfahan University of Medical Sciences

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international@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Parvin Sajedi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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

Not applicable