

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the effect of intrathecal Bupivacaine with intrathecal Ropivacaine on Hemodynamic of patients under Elective Caesarean Section

Protocol summary

Study aim

Comparison of the Effect of Intrathecal Bupivacaine with Intrathecal Ropivacaine on Hemodynamic of Patients under Elective Caesarean Section

Design

This Study will be done as a Randomized Double-Blind Clinical Trial with 2 parallel groups. 72 Pregnant women with simple randomization method divided into 2 groups: We provide 36 Blue cards (for B group) & 36 Red cards (for R group), place each card in pocket, close pockets & leave them in a Package, Disarrange pockets, then take a pocket randomly without replacing & register subsequence of cards from 1 to 72 & patients will take drugs upon performed subsequence respectively

Settings and conduct

After the grace of ethics committee of Ardabil University, this study will be done in Alavi hospital. We explain the Procedure for patients & obtain satisfaction. Blinds of study are patients & Evaluator. After intravenously hydration & cardiopulmonary monitoring, Spinal Anesthesia under aseptic condition will be performed. Hemodynamic parameters & side effect of drugs will be recorded & Statistical comparison will be done

Participants/Inclusion and exclusion criteria

-Entrance Criteria: Term Pregnant Women; 18-40 y/o; Physical health class (ASA score): 1-2; Candidated for Caesarean section -Non Entrance Criteria: Dissatisfaction of Patient for Spinal Anesthesia; Presence of Contraindication for Regional Anesthesia; Pre-term or Post-term Pregnancy; Age<18 or Age>40 y/o; ASA score>2; Urgency Surgery

Intervention groups

Group B: Amp. Bupivacaine 0.5%, 12mg, Single dose, Intrathecally Group R: Amp. Ropivacaine 0.5%, 18mg, Single dose, Intrathecally

Main outcome variables

Age; Drug group; ASA score; Heart rate; systolic blood

pressure; Mean arterial pressure; Decrease of blood pressure; Bradycardia; Nausea or vomiting; Anesthesia level>T4; Time of Decreasing of anesthesia level; Surgeon's Satisfaction rate about quality of relaxation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190506043495N1**

Registration date: **2019-05-18, 1398/02/28**

Registration timing: **prospective**

Last update: **2019-05-18, 1398/02/28**

Update count: **0**

Registration date

2019-05-18, 1398/02/28

Registrant information

Name

Elham Habibzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3372 6162

Email address

e.habibzadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of intrathecal Bupivacaine with intrathecal Ropivacaine on Hemodynamic of patients under Elective Caesarean Section

Public title
Spinal Anaesthesia with Bupivacaine versus Ropivacaine in Caesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Term Pregnant women 18 - 40 Y/O Physical health class (ASA score): 1-2 Candidated for Caesarean section
Exclusion criteria:
Dissatisfaction of Patient for Spinal Anaesthesia Presence of Contraindication for Regional Anaesthesia Pre-term or post-term pregnancy Age<18 y/o or Age>40 y/o Physical health class (ASA score) > 2 Urgency surgery

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization will be done: we provide 36 Blue cards (for Bupivacaine group) and 36 Red cards (for Ropivacaine group), Place each card in pocket, Close pockets and leave them in package, Disarrange pockets, then take a pocket randomly without replacing and register subsequence of cards from 1 to 72 and patients will take drugs upon performed subsequence respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are first blind group without aware from type of given drug. Evaluator of outcomes is second blind that will not presence on anaesthesia time.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil Complex University, Daneshgah st.

City

Ardabil

Province

Ardabil

Postal code

5618985991

Approval date

2019-05-06, 1398/02/16

Ethics committee reference number

IR.ARUMS.REC.1398.042

Health conditions studied

1

Description of health condition studied

Spinal Anaesthesia in Caesarean section

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart rate

Timepoint

Before Spinal Anaesthesia and every 2 minutes interval after Spinal Anaesthesia

Method of measurement

Heart monitoring device

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

Before Spinal Anaesthesia and every 2 minutes interval after Spinal Anaesthesia

Method of measurement

Non invasive automated blood pressure device

Intervention groups

1

Description

Intervention group: Amp. Bupivacaine 0.5% 12.5 mg,
Single dose, Intrathecally

Category

Treatment - Other

2

Description

Intervention group: Amp. Ropivacaine 0.5%, 17.5 mg,
Single dose, Intrathecally

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi hospital

Full name of responsible person

Soheila Mousavi

Street address

alavi hospital, Shahid Maadi Ave.

City

Ardabil

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5613974156

Phone

+98 45 3324 8888

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+98 45 3323 7821

Email

alavi@arums.ac.ir

Web page address

<http://www.arums.ac.ir/alavi/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Godrat Akhavan Akbari

Street address

Daneshgah st., Ardabil Complex University

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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

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Ahmad ghazi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Alavi Hospital, Shahid Maadi Ave.

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Contact

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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

Person responsible for updating data**Contact****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Ahmad Ghazi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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