

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

A prospective randomized controlled study comparing 0.75% hyperbaric ropivacaine with 0.5% hyperbaric bupivacaine in spinal anesthesia for elective caesarean delivery

Protocol summary

Study aim

To compare 0.75% Hyperbaric Ropivacaine with 0.5% Hyperbaric Bupivacaine in Spinal anaesthesia for caesarean delivery in terms of onset and duration of sensory and motor block

Design

1. A prospective, phase 3, single-centre, randomised, controlled, double-blind study involving 49 adult pregnant women in each group who are scheduled to have an elective caesarean delivery, enrolled between August 2023 and April 2024.

Settings and conduct

The study will be conducted at the obstetric unit of tertiary care facility Tata Main Hospital in Jamshedpur, India's eastern region. The concerned anesthesiologist will administer the spinal block in accordance with group assignment after obtaining informed consent from the participants, who will be randomly assigned to one of the two groups using the sealed envelope simple randomization method. Then principle investigator will observe and collect data.

Participants/Inclusion and exclusion criteria

Inclusion criteria- 1. Adult pregnant women (Age $\geq$ 18 Years) undergoing elective caesarean delivery under spinal anaesthesia 2. ASA grades I and II Exclusion criteria 1. Pre-term Pregnancy (<37 weeks of Gestational age) 2. Patients having obstetric complications (psychiatric, neurologic, cardiac or hemologic disease, diabetes, multiple gestation, preeclampsia, eclampsia, bleeding, or coagulation disorder) 3. Patients with evidence of foetal compromise 4. Patients with heights of 150 cm or > 180 cm 5. Patients with BMI $\geq$ 30 6. Patient with history of allergy to Ropivacaine or Bupivacaine

Intervention groups

Group B: 2.6 ml of 0.5% heavy Bupivacaine Group R: 2.6 ml of 0.75% heavy Ropivacaine

Main outcome variables

To determine the duration of motor blockade monitored by the Bromage scale after spinal anaesthesia in adult women undergoing elective caesarean section with 0.75% Hyperbaric Ropivacaine and 0.5% Hyperbaric Bupivacaine.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221109056455N1**

Registration date: **2023-07-25, 1402/05/03**

Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**

Update count: **0**

Registration date

2023-07-25, 1402/05/03

Registrant information

Name

RISHI ANAND

Name of organization / entity

TATA MAIN HOSPITAL

Country

India

Phone

+91 97165 48587

Email address

rishi.anand1@tatasteel.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2024-04-01, 1403/01/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A prospective randomized controlled study comparing 0.75% hyperbaric ropivacaine with 0.5% hyperbaric bupivacaine in spinal anesthesia for elective caesarean delivery

Public title
Effect of hyperbaric Ropivacaine in comparison to Bupivacaine for spinal anaesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
ASA physical status 1 and 2 Pregnant adults for elective caesarean section
Exclusion criteria:
Allergy to Ropivacaine or Bupivacaine Infection at the site for spinal anaesthesia Patient with evidence of foetal distress Short stature (150 cm) Tall stature (>180 cm) Obesity(BMI>30) Patient with an obstetrical complication (multiple gestations, bleeding, gestational hypertensive diseases) Psychiatric or seizure disorder Bleeding disorder Cardiac disease

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will employ simple randomization using the sealed envelope method. Randomly generated treatment allocations will be given to participating clinicians in sealed, opaque envelopes. A patient is administered the assigned treatment regimen after their consent to participate in the trial has been obtained.

Blinding (investigator's opinion)
Double blinded

Blinding description
The trial will employ the sealed envelope technique. The anesthesiologist who will be providing care will open the randomly selected sealed envelope, give the patient the appropriate medication, and record it in a document next to the patient's recruitment number. The name of the drug will not be disclosed to the investigator until the

study is over. The medication will be given to the patient without her knowledge of the drug's name. An observer who is blind to the drugs given will monitor the patient both during surgery and in the recovery room. The research investigator will receive a document with the name of the drug that was administered against the participant recruitment number at the time of data analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Ethics Committee Tata Main Hospital, Jamshedpur

Street address

Road C, Northern town, Bistupur, Jamshedpur

City

Jamshedpur

Postal code

831001

Approval date

2022-06-06, 1401/03/16

Ethics committee reference number

TMH/IEC/JUNE/009/2022

Health conditions studied

1

Description of health condition studied

Delivery by elective Caesarian section

ICD-10 code

O82.0

ICD-10 code description

Single delivery by elective caesarean section

Primary outcomes

1

Description

Duration of motor blockade monitored by Bromage scale

Timepoint

30 min

Method of measurement

Bromage score

Secondary outcomes

1

Description

onset of sensory blockade

Timepoint

every 2 minutes after spinal block

Method of measurement

pin prick method

2

Description

onset of motor blockade

Timepoint

every 2 minutes after spinal block.

Method of measurement

Modified Bromage score

Intervention groups

1

Description

Group B. 2.6 ml of Bupivacaine 0.5 % heavy intrathecal

Category

Treatment - Drugs

2

Description

Group R : 2.6 ml of Ropivacaine 0.75 % heavy intrathecal

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tata main hospital, Jamshedpur, India

Full name of responsible person

Dr. Umesh Kumar Singh

Street address

C Road, Bistupur

City

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Postal code

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+91 92046 51673

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Web page address

<https://www.tatamainhospital.com>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tata Main Hospital, Jamshedpur

Full name of responsible person

Dr Umesh Kumar Singh

Street address

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Grant name

Not applicable

Grant code / Reference number

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

Yes

Title of funding source

Tata Main Hospital, Jamshedpur

Proportion provided by this source

100

Public or private sector

Private

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

Tata Main Hospital

Full name of responsible person

Dr Gunjan Wadhwa

Position

DNB resident

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

IPD data about all observations (primary and secondary outcomes, demographics)

When the data will become available and for how long

10 years after completion of study

To whom data/document is available

people working in academics

Under which criteria data/document could be used

for meta analysis and review of literature.

From where data/document is obtainable

Through request to the principal investigator or corresponding author after publication

What processes are involved for a request to access data/document

emailed request letter citing purpose and credentials of applicant

Comments