Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ≥ 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 ≥ 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 Ropivacine 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
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831001
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tata Main Hospital, Jamshedpur
Full name of responsible person
Dr Umesh Kumar Singh
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Phone
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Email
druks@tatasteel.com
Web page address
https://www.tatamainhospital.com/
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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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