Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effects of intravenous ondansetron, paracetamol and both drugs in prevention of post-dural puncture headache following spinal anaesthesia for caesarean section;A double-blind randomised controlled trial.

Protocol summary

Study aim

To compare the effects of intravenous ondansetron, paracetamol, and both drugs in prevention of post dural puncture headache following spinal anaesthesia for caesarean section.

Design

A total of 176 participants will be randomly divided into 4 groups of 44 per group. Superiority, parallel group trial with blinded outcome assessment will be used. Randomisation will be centralised and computerised with concealed randomisation sequence to be carried out at an external site.

Settings and conduct

The study centres will be UNTH ,ESUTTH and MCSH, Enugu. The trial will be double-blind study in which the study participants and outcome assessors will be blinded from knowing what intervention was given to the participants.

Participants/Inclusion and exclusion criteria

The participants' inclusion criteria comprised booked patient at term ,18 – 40-year-old and ASA I and II parturients undergoing elective caesarean section under spinal anaesthesia. The exclusion criteria comprised patients with known contraindication to spinal anaesthesia,allergy to the study drugs,patients with comorbidities like pregnancy induced hypertension, gestational diabetes mellitus, coronary artery disease or heart disease etc ,Patients converted into general anaesthesia,repeated dural punctures and patients who will decline consent to participate despite adequate counselling

Intervention groups

A total of 176 participants booked for elective caesarean section will be randomly divided into 4 groups. Each group will comprise 44 participants. Groups 1,2,3 and 4 will receive 8mg of intravenous(IV) ondansetron only ,600mg of IV paracetamol, both IV ondansetron,8mg and paracetamol,600mg, and water for injection(placebo) respectively.

Main outcome variables

The primary outcome measure will be the incidence of post dural puncture headache within 24 hours following caesarean delivery.

General information

Reason for update

Acronym

PDPHT

IRCT registration information

IRCT registration number: **IRCT20241028063524N2**
Registration date: **2024-12-27, 1403/10/07**
Registration timing: **prospective**

Last update: **2024-12-27, 1403/10/07**
Update count: **0**

Registration date

2024-12-27, 1403/10/07

Registrant information

Name

Leonard Ajah

Name of organization / entity

Faculty of Clinical Sciences,University of Nigeria, Enugu Campus

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-02-01, 1403/11/13
Expected recruitment end date
2025-07-31, 1404/05/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of intravenous ondansetron, paracetamol and both drugs in prevention of post-dural puncture headache following spinal anaesthesia for caesarean section;A double-blind randomised controlled trial.

Public title
Comparison of the effects of intravenous ondansetron, paracetamol and both drugs in prevention of post-dural puncture headache following spinal anaesthesia for caesarean section;A double-blind randomised controlled trial.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Booked patient at term attending antenatal care at the study centers. 18 – 40-year-old. ASA I and II parturients undergoing elective caesarean section under spinal anaesthesia.
Exclusion criteria:
Patients with known contraindication to spinal anaesthesia Allergy to the study drugs Patients with comorbidities like pregnancy induced hypertension, gestational diabetes mellitus, coronary artery disease or heart disease Patients taking drugs like selective serotonin receptor inhibitors (SSRIs) Patients converted into general anaesthesia
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **176**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization of 176 pregnant women will be accomplished utilizing a computer-generated randomization schedule (Stat-Trek Generator), and placed into consecutively numbered, opaque, sealed envelopes. The eligible women will be assigned by means of these computer-generated random numbers into 4 sample groups; intervention group A (will receive Ondansetron alone), intervention group B(will receive Paracetamol alone), intervention group C(will receive combination of ondansetron and paracetamol) and control group D(will receive water for injection) .Thus, once the patient is deemed eligible and has given informed consent, she will be assigned a sequential study number. Block randomization of all eligible consenting patients will be done using computer generated random sequence and a randomization ratio of 1:1:1: 1. Upon enrolment, an opaque envelope containing the patient enrolment number and assignment to any of the groups,will be opened and the unique number placed on the patient's antenatal card. Each participant will be assigned a unique subject number for identity and confidentiality.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants and the outcome assessors will not know which injection will be given to any of the participants.
Placebo
Used
Assignment
Parallel
Other design features
Already described in the randomization section

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
University of Nigeria Teaching Hospital Research and Ethics Committee
Street address
Ituku-Ozalla
City
Enugu
Postal code
40001
Approval date
2024-11-27, 1403/09/07
Ethics committee reference number
UNTH/HREC/2024/11/3047

Health conditions studied

1

Description of health condition studied
Post-dural puncture headache is a headache that develops within 5 days after dural puncture which worsens in an upright position and improves with lying

down and accompanied by neck stiffness, tinnitus, photophobia, and nausea.

ICD-10 code

082.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

The primary outcome measure will be the incidence of post dural puncture headache within 24 hours following caesarean delivery.

Timepoint

At 6,12,18 and 24 hours post-caesarean section.

Method of measurement

This will be assessed using the visual analogue scale

Secondary outcomes

1

Description

Maternal complications (spinal anaesthesia induced hypotension, intra operative and post operative nausea and vomiting)

Timepoint

1 hour,6 hours,12 hours,18 hours,24 hours

Method of measurement

Blood pressure check and report of any incidence of nausea and vomiting

2

Description

Neonatal complications (Apgar scores at 1 and 5 min, the need for cardiopulmonary resuscitation and admission to the neonatal intensive care unit (NICU) during the first 24 hours after delivery will be assessed too).

Timepoint

1 minute,5 minutes, 24 hours

Method of measurement

APgar scoring and report of any incidence of the above interventions

Intervention groups

1

Description

Intervention group A:This group will receive 8mg and 600mg of intravenous ondansetron and paracetamol respectively.

Category

Treatment - Drugs

2

Description

Intervention group B will receive 8mg of intravenous ondansetron

Category

Treatment - Drugs

3

Description

Intervention group C will receive 600mg of intravenous paracetamol

Category

Treatment - Drugs

4

Description

Control group D will receive water for injection (placebo).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Nigeria Teaching Hospital

Full name of responsible person

Dr. Ogwueleka, Chukwudubem Vitalis

Street address

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center

Mother of Christ Specialist Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Nigeria Teaching Hospital,Enugu,Nigeria
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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
University of Nigeria Teaching Hospital,Enugu,Nigeria
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
University of Nigeria Teaching Hospital,Enugu,Nigeria
Full name of responsible person
Dr . Ogwueleka, Chukwudubem Vitalis
Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data will be provided only on request.

When the data will become available and for how long

It will be provided after publication of the project and last for 2 years

To whom data/document is available

It will be provided to the publishing journal

Under which criteria data/document could be used

For secondary analysis of the data and for understudy of the data by another researcher.

From where data/document is obtainable

The journal that will publish the research work or by contacting Prof. Leonard O. Ajah through leonard.ajah@unn.edu.ng

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

It requires writing the corresponding author and stating the aim of the request of the data

Comments

Already stated above