

The analgesic effects of bupivacaine with fentanyl, dexamethasone or midazolam combinations for labour analgesia

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		<input type="checkbox"/> Protocol
Registration date 28/04/2026	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/04/2026	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Many women experience strong pain during labour. Good pain relief can help women feel more comfortable and improve their overall experience of childbirth. This study looked at different drug combinations used in spinal anaesthesia to ease labour pain. The aim was to find out which combination of medicines works best, how quickly they start working, how long the pain relief lasts, how safe each option is for mothers and babies, and how satisfied women are with the pain relief they receive.

Who can participate?

Healthy pregnant women aged 18 to 45 years who were in active labour with the cervix open between 4 and 6 centimetres could take part. All participants needed to give consent and be medically assessed as suitable for spinal anaesthesia.

What does the study involve?

Women who agreed to take part were randomly placed into one of several groups. Each group received a different mixture of medicines injected into the lower back to relieve labour pain. These mixtures included low-dose bupivacaine on its own or combined with fentanyl, dexamethasone or midazolam. A placebo group received saline instead of an active drug combination. Neither the women nor the researchers knew which mixture was given, which helped make the study fair.

After the injection, the women's vital signs were checked often. Their level of pain, the time it took for the pain relief to start, how long it lasted, any side effects and their satisfaction with the pain relief were recorded. Blood samples were taken before and after delivery to look for possible changes in blood parameters. Newborn health was assessed using the routine APGAR scoring system.

What are the possible benefits and risks of participating?

The study may have offered women effective pain relief during labour. Taking part also helped researchers learn more about which drug combinations are safest and most effective. Risks were

the same as those normally linked with spinal anaesthesia. These may include low blood pressure, nausea, itching, a slow or fast heart rate or, rarely, nerve-related complications. The researchers monitored mothers and babies closely to ensure their safety.

Where is the study run from?

The study was carried out at Tamale Teaching Hospital in the northern region of Ghana.

When is the study starting and how long is it expected to run for?

The first participant was enrolled on 1 August 2024, and the final participant was enrolled on 20 October 2024. The study was completed on 1 October 2025.

Who is funding the study?

The study is funded by the research team and is investigator initiated. The sponsor is C. K. Tedam University of Technology and Applied Sciences (Ghana)

Who is the main contact?

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Contact information

Type(s)

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Study information

Scientific Title

The analgesic effects of bupivacaine with fentanyl, dexamethasone or midazolam combinations for labour analgesia: a comparative study

Study objectives

1. To investigate the analgesic effects of intrathecal injection of low-dose bupivacaine with fentanyl, dexamethasone or midazolam combinations for labour pain management.

2. To investigate the side effects of low-dose bupivacaine with fentanyl, dexamethasone or midazolam combinations on mothers and the neonate.
3. To assess patients' satisfaction with pain relief through the administration of low-dose bupivacaine with fentanyl, dexamethasone or midazolam combinations for labour analgesia.
4. To investigate the effects of intrathecal low-dose bupivacaine with fentanyl, dexamethasone or midazolam combinations on patients' haematological parameters.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 19/03/2025, Tamale Teaching Hospital Ethical Review Committee (P O Box TL 16, Tamale, +2332, Ghana; +233 372000180; research.development@tth.gov.gh), ref: TTHERC/20/03/25/05

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Dose comparison

Assignment

Single

Purpose

Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Labour analgesia

Interventions

Spinal anaesthesia/analgesia will be carried out on each participant using the drug mixtures assigned to the various groups to manage their labour pain.

History will be taken from all the subjects at the pre-natal ward. These included their weight, age, gestational age, progress of the pregnancy, parity, maternal health history, bleeding disorders, pre-existing neurological deficits, anaesthesia-related obstetric history, airway assessment, back examination for any deformity, baseline vital signs including blood pressure, pulse rate and respiration will be taken and recorded. Laboratory investigations will be carried out to assess full blood count parameters. Intravenous access will be obtained with 16/18-gauge cannula and patients pre-loaded with 500mls of crystalloids (0.9% saline/ ringers lactate). The participants will be placed in a sitting or lateral position and their lumbar region cleaned with savlon and methylated spirit to keep the area sterile. The needle insertion point will be located

by the researchers using the landmarks such as the posterior superior iliac spine and the tuffier's line. Lumbar vertebrae three and four interspace (L3/L4) or lumbar vertebrae four and five interspace (L4/L5) will be identified as the needle insertion points. Lidocaine 2% will be used to infiltrate the skin at the needle insertion point to minimise pain and discomfort to the patients. Lumbar puncture will then be performed with a 25G/26G pencil point Whitacre spinal needle, which will be confirmed by observing free flow cerebrospinal fluid from the spinal needle.

Patients will be randomised and assigned to the following groups: Group A: Bupivacaine + Fentanyl, Group B: Bupivacaine + Dexamethasone, Group C: Bupivacaine + Midazolam, Group D: Bupivacaine alone and Group E: Placebo.

Computer randomization will be adopted and both investigators and participants will be blinded in order to minimise bias. Groups A, B and C will form the study groups whilst group D will be the control group.

An intrathecal injection of low-dose 0.5% heavy bupivacaine hydrochloride by Aspen pharmacare, CAS RN 73360-54-0/ ATC Code N01BB01 (2.5mg) + fentanyl (25mcg) by Martindale pharmaceutical Ltd, PL OO156/0038 will be administered to participants in group A, those in group B will receive intrathecal injection of low-dose bupivacaine (2.5mg) + 2mg of dexamethasone with the brand name Dexataj, group C subjects will have intrathecal injection of low-dose bupivacaine (2.5mg) + midazolam (2mg) with batch number EP 15122303 by Verve company while group D (Control Group) participants will receive intrathecal injection of low-dose bupivacaine (2.5mg) + normal saline. After the spinal anaesthesia, participants will be advised to stay in bed for about twenty minutes and will then be assisted to ambulate when the block is settled. Vital signs of participants will be monitored every minute for the first five minutes then fifteen (15) minutes, thirty (30) minutes, forty (45) minutes and sixty (60) minutes interval for possible complications.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Bupivacaine, fentanyl, dexamethasone, midazolam

Primary outcome(s)

1. Pain intensity measured using Numerical Pain Rating Scale (0–10) at Baseline, every minute for first 5 minutes, then at 10, 15, 30, 45, 60, 90, 120, 150 and 180 minutes

Key secondary outcome(s)

1. Onset and duration of analgesia measured using Time to pain score ≤ 3 (onset) and time from onset to recurrence of pain requiring intervention (duration) at Continuously assessed from drug administration up to 180 minutes

2. Maternal adverse effects (hypotension, heart rate abnormalities, respiratory depression, nausea/vomiting, pruritus, shivering, neurological symptoms, etc.) measured using Clinical monitoring (blood pressure apparatus, pulse oximeter), 3-point ordinal scale for nausea/vomiting and standardized clinical definitions at Every 2–3 minutes for first 15 minutes, every 5 minutes for next 30 minutes then every 15 minutes thereafter

3. Neonatal well-being (Apgar score, resuscitation need, NICU admission, early complications) measured using APGAR scoring system and clinical observation/recording at 1 minute and 5 minutes after birth; within first 24 hours for NICU admission and complications

4. Patient satisfaction measured using Structured questionnaire at Post-delivery (after completion of labour and analgesia experience)

Completion date

01/10/2025

Eligibility

Key inclusion criteria

1. Consented labouring women
2. Classified as ASA I and ASA II (American Society of Anaesthesiologist)
3. Cervical dilatation of 4cm-6cm

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 years

Upper age limit

45 years

Sex

Female

Total final enrolment

150

Key exclusion criteria

1. Contraindications to spinal anaesthesia
2. Allergic to any of the proposed drugs
3. ASA III classification and above
4. Cannot consent for themselves

Date of first enrolment

01/08/2024

Date of final enrolment

20/10/2024

Locations

Countries of recruitment

Ghana

Sponsor information

Organisation

C.K. Tedam University of Technology and Applied Sciences

ROR

<https://ror.org/00kpq4k75>

Funder(s)

Funder type

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available