



Clinical trial results:

Does subarachnoid administration of hyperbaric prilocaine produce an improved recovery from anaesthesia when compared with hyperbaric bupivacaine when used to facilitate cervical cerclage in pregnant women at risk of pre-term loss?

A randomised controlled superiority Phase IV trial

Summary

EudraCT number	2019-001548-23
Trial protocol	GB
Global end of trial date	10 September 2025

Results information

Result version number	v1 (current)
This version publication date	01 October 2026
First version publication date	01 October 2026
Summary attachment (see zip file)	PRILOCC_Clinical_Study Report_Docusigned (PRILOCC_Clinical_Study Report_Docusigned.pdf)

Trial information

Trial identification

Sponsor protocol code	225703
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Guy's and St Thomas NHS Foundation Trust
Sponsor organisation address	Great Maze Pond, London, United Kingdom, SE1 9RT
Public contact	Dr Desire Onwochei, Guy's & St. Thomas' NHS Foundation Trust , +44 02071880645, Desire.Onwochei@gstt.nhs.uk
Scientific contact	Dr Desire Onwochei, Guy's & St. Thomas' NHS Foundation Trust , +44 02071880645, Desire.Onwochei@gstt.nhs.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No
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Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 August 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 April 2025
Global end of trial reached?	Yes
Global end of trial date	10 September 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine if subarachnoid hyperbaric 2% prilocaine produces a clinically meaningful reduction in time taken for regression of lower limb motor block when compared to hyperbaric 0.5% bupivacaine

Protection of trial subjects:

The trial was conducted according to the protocol and in compliance with the principles of the Declaration of Helsinki (1996) as amended, the principles of Good Clinical Practice (GCP) and in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, the Research Governance Framework for Health and Social Care, the Data Protection Act 1998 and other regulatory requirements as appropriate. The trial protocol and substantial amendments were reviewed by the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA).

Participants have the right to withdraw from the study at any time for any reason. The investigator also has the right to withdraw patients from the study drug in the event of inter-current illness, AEs, SAE's, SUSAR's, protocol violations, administrative reasons or other reasons. It is understood by all concerned that an excessive rate of withdrawals can render the study un-interpretable; therefore, unnecessary withdrawal of patients should be avoided. Should a patient decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible.

The participant will be made aware of their right to withdraw at any time from the trial without giving reasons and without prejudicing his/her further treatment and will be provided with a contact point where he/she may obtain further information about the trial. The right of the participant to refuse participation without giving reasons will be respected.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 November 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 135
Worldwide total number of subjects	135
EEA total number of subjects	135

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	135
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	135
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Number of subjects completed	135
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Period 1

Period 1 title	Overall Trial (overall period)
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Is this the baseline period?	Yes
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Allocation method	Randomised - controlled
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Blinding used	Double blind
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Roles blinded	Subject, Investigator, Monitor, Carer, Assessor
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Blinding implementation details:

Prospective, parallel group, double-blind, randomised, controlled, superiority trial.

Arms

Are arms mutually exclusive?	Yes
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Arm title	PRILOCAINE
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Arm description:

Intervention - Subarachnoid block (SAB) with 40 mg (2 ml) of hyperbaric 20 mg/ml prilocaine and 15 mcg (0.3 ml) fentanyl (50 mcg/ml).

Arm type	Experimental
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Investigational medicinal product name	Prilocaine (hyperbaric 2%), 20mg/ml hyperbaric solution for injection
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Solution for injection
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Routes of administration	Injection
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Dosage and administration details:

Dosing Regimen:

Dose: 40 mg (2 ml)

Supplement: Fentanyl 15 mcg

Route: intrathecal (SAB)

Number of participants (planned and analysed)

Arm title	BUPIVICAINE
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Arm description:

Hyperbaric (heavy) 0.5% Bupivacaine

Dose: 10 mg (2 ml)

Supplement: Fentanyl 15 mcg

Route: Intrathecal (SAB)

Arm type	Active comparator
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Investigational medicinal product name	Hyperbaric (heavy) 0.5% Bupivacaine
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Solution for injection
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Routes of administration	Intratracheal use
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Dosage and administration details:

Hyperbaric (heavy) 0.5% Bupivacaine

Dose: 10 mg (2 ml)

Supplement: Fentanyl 15 mcg

Route: Intrathecal (SAB)

Number of subjects in period 1	PRILOCAINE	BUPIVICAINE
Started	68	67
Completed	66	67
Not completed	2	0
Physician decision	1	-
Consent withdrawn by subject	1	-

Baseline characteristics

Reporting groups

Reporting group title	PRILOCAINE
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Reporting group description:

Intervention - Subarachnoid block (SAB) with 40 mg (2 ml) of hyperbaric 20 mg/ml prilocaine and 15 mcg (0.3 ml) fentanyl (50 mcg/ml).

Reporting group title	BUPIVICAINE
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Reporting group description:

Hyperbaric (heavy) 0.5% Bupivacaine

Dose: 10 mg (2 ml)

Supplement: Fentanyl 15 mcg

Route: Intrathecal (SAB)

Reporting group values	PRILOCAINE	BUPIVICAINE	Total
Number of subjects	68	67	135
Age categorical Units: Subjects			
Adults (18-64 years)	68	67	135
Gender categorical Units: Subjects			
Female	68	67	135
Male	0	0	0

End points

End points reporting groups

Reporting group title	PRILOCAINE
Reporting group description: Intervention - Subarachnoid block (SAB) with 40 mg (2 ml) of hyperbaric 20 mg/ml prilocaine and 15 mcg (0.3 ml) fentanyl (50 mcg/ml).	
Reporting group title	BUPIVICAINE
Reporting group description: Hyperbaric (heavy) 0.5% Bupivacaine Dose: 10 mg (2 ml) Supplement: Fentanyl 15 mcg Route: Intrathecal (SAB)	

Primary: Efficacy

End point title	Efficacy ^[1]
End point description:	
End point type	Primary
End point timeframe: The time taken in minutes from initiation of subarachnoid block (SAB) until regression of motor block as assessed using the Bromage score of I.	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: View Uploaded Report	

End point values	PRILOCAINE	BUPIVICAINE		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	68	67		
Units: minutes				
arithmetic mean (standard deviation)	88 (± 51)	129 (± 63)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Postoperatively and at 24-hour follow-up, the patient will be assessed for any potential adverse events related to the technique or the IMPs.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	PRILOCAINE
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Reporting group description: -

Reporting group title	BUPIVICAINE
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Reporting group description: -

Serious adverse events	PRILOCAINE	BUPIVICAINE	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 68 (4.41%)	2 / 67 (2.99%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Pregnancy, puerperium and perinatal conditions			
Early miscarriage			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spontaneous rupture of membranes			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Urinary retention			

subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	PRILOCAINE	BUPIVICAINE	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 68 (13.24%)	1 / 67 (1.49%)	
Investigations			
Magnetic resonance imaging			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
Spinal anaesthesia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Vasovagal syncope			
subjects affected / exposed	2 / 68 (2.94%)	1 / 67 (1.49%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	4 / 68 (5.88%)	0 / 67 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 October 2019	AM9 (NSA7) Study extension & PI change at KCH
18 February 2020	Initial Protocol / ICF / Poster / GP letter / 24hr phone fup v1 14Oct19 PIS v1 18Oct19 SmPC Bupivacaine (15May15), SmPC Prilotekal (13Dec17) Revised documents: Protocol v1 24Jan20, ICF v2 09Apr20 PIS v2 19Apr20, Poster v2 09Apr20
13 September 2021	AM1 (NSA1) Protocol v1.1 31Aug21 Changes to primary objective, inclusion/exclusion & routine intraoperative procedures etc.
07 February 2022	AM2 (NSA2) Addition of 2 new sites (The trial to become multi-centre): Royal Sussex County Hospital (PI: Abigail Medniuk) Musgrove Park Hospital (PI: Madhavi Keskar) N.b. this amendment covered the addition of sites only. Study documents reflecting the new multi-centre status of the trial were updated as part of NSA4
15 March 2022	AM3 (NSA3) GP letter v2 05Nov21 Change of PI from Kate Cheeseman to Desire Onwochei
12 August 2022	AM4 (NSA4) Study documents were not updated accordingly at the time of the previous amendment, so this amendment seeks to rectify this. Single to multi-centre trial. Protocol v1.2 20May22 PIS, ICF, GP letter & 24hr phone fup v3 25May22 Change of PI at Royal Sussex to James Wicker
10 January 2023	AM5 (NSA5) New Site: KCH
13 July 2023	AM7 (NSA6) Study extension
19 August 2024	AM8 (SA1) Change of CI/PI to Dr Neel Desai Change of the CI who also serves as the PI, due to upcoming maternity leave starting on 19/04/2024, which includes updates to the protocol, PIS, ICF, Poster and GP letter; Updates to the protocol to align with recent revisions to the pharmacovigilance policy.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported