



## Clinical trial results:

### Comparison of ultrasound-guided PENG block and supra-inguinal fascia iliaca compartment block for postoperative pain and early motor recovery after total hip arthroplasty: a randomized controlled non-inferiority clinical trial

#### Summary

EudraCT number	2020-005126-28
Trial protocol	BE
Global end of trial date	06 July 2022

#### Results information

Result version number	v1 (current)
This version publication date	03 June 2026
First version publication date	03 June 2026
Summary attachment (see zip file)	Publication (comparison_between_supra_inguinal_fascia_iliaca.8.pdf)

#### Trial information

##### Trial identification

Sponsor protocol code	NA
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##### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	CHU de Liège
Sponsor organisation address	Sart Tilman B35, Liège, Belgium,
Public contact	Michele Carella, CHU de Liège, mcarella@chuliege.be
Scientific contact	Michele Carella, CHU de Liège, mcarella@chuliege.be

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

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 July 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 July 2022
Global end of trial reached?	Yes
Global end of trial date	06 July 2022
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

In this study we primarily aimed at evaluating the influence of ropivacaine SFICB or PENG block on postoperative pain at rest and at mobilization in patients receiving spinal anesthesia for THAPL and the non-inferiority of PENG block on postoperative pain, opioid-sparing and global functional outcomes.

Protection of trial subjects:

After a detailed explanation about the study rationale by the principal investigator, written informed consent was obtained before inclusion of eligible patients into the trial. This study follows the applicable CONSORT guidelines and was performed in accordance with the most recent version of the Helsinki Declaration. Data acquisition occurred between 11 October 2021 and 6 July 2022 at the University Hospital of Liege, Belgium.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 October 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 106
Worldwide total number of subjects	106
EEA total number of subjects	106

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)	5
From 65 to 84 years	89

85 years and over	12
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## Subject disposition

### Recruitment

Recruitment details:

Data acquisition occurred between 11 October 2021 and 6 July 2022 at the University Hospital of Liege, Belgium.

Patients scheduled to undergo elective PLTHA under spinal anaesthesia were consecutively and prospectively considered as eligible for inclusion.

### Pre-assignment

Screening details:

Patients scheduled to undergo elective PLTHA under spinal anaesthesia

### Period 1

Period 1 title	Main period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	SFIB

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Ultrasound-guided supra-inguinal fascia iliaca block (SFIB) performed after spinal anaesthesia. Single perineural injection of 40 mL ropivacaine 0.375% in the fascia iliaca compartment to target femoral, lateral femoral cutaneous, and obturator nerve branches. No catheter placement.

<b>Arm title</b>	PENG
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Ultrasound-guided pericapsular nerve group (PENG) block performed after spinal anaesthesia. Single perineural injection of 20 mL ropivacaine 0.75% into the fascial plane between the psoas tendon and pubic ramus. No catheter left in situ.

Number of subjects in period 1	SFIB	PENG
Started	53	53
Completed	53	53

## Period 2

Period 2 title	Recruitment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Assessor

## Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	PENG

Arm description:

PENG with 20ml of ropivacaine 0.75%

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Ultrasound-guided pericapsular nerve group (PENG) block performed after spinal anaesthesia. Single perineural injection of 20 mL ropivacaine 0.75% into the fascial plane between the psoas tendon and pubic ramus. No catheter left in situ.

<b>Arm title</b>	SFIB
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Arm description:

SFIB with 40ml of ropivacaine 0.375%

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Ultrasound-guided supra-inguinal fascia iliaca block (SFIB) performed after spinal anaesthesia. Single perineural injection of 40 mL ropivacaine 0.375% in the fascia iliaca compartment to target femoral, lateral femoral cutaneous, and obturator nerve branches. No catheter placement.

<b>Number of subjects in period 2</b>	PENG	SFIB
Started	53	53
Completed	51	51
Not completed	2	2
Protocol deviation	2	2

## Baseline characteristics

### Reporting groups

Reporting group title	Main period
Reporting group description: -	

Reporting group values	Main period	Total	
Number of subjects	106	106	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	5	5	
From 65-84 years	89	89	
85 years and over	12	12	
Age continuous			
Units: years			
arithmetic mean	66.5		
standard deviation	± 11.6	-	
Gender categorical			
Units: Subjects			
Female	61	61	
Male	45	45	

### Subject analysis sets

Subject analysis set title	SFIB group
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Group SFIB	
Subject analysis set title	PENG group
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
PENG group	

Reporting group values	SFIB group	PENG group	
Number of subjects	51	51	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	

Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	3	2	
From 65-84 years	42	43	
85 years and over	6	6	
Age continuous			
Units: years			
arithmetic mean	64.8	68.2	
standard deviation	± 12.7	± 10.5	
Gender categorical			
Units: Subjects			
Female	30	27	
Male	21	24	



## End points

### End points reporting groups

Reporting group title	SFIB
Reporting group description: -	
Reporting group title	PENG
Reporting group description: -	
Reporting group title	PENG
Reporting group description:	
PENG with 20ml of ropivacaine 0.75%	
Reporting group title	SFIB
Reporting group description:	
SFIB with 40ml of ropivacaine 0.375%	
Subject analysis set title	SFIB group
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Group SFIB	
Subject analysis set title	PENG group
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
PENG group	

### Primary: Rest NRS pain 6h postop

End point title	Rest NRS pain 6h postop
End point description:	
Rest pain	
End point type	Primary
End point timeframe:	
6 hours after surgery	

End point values	PENG	SFIB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	51		
Units: NRS 0-10				
number (confidence interval 95%)				
NRS	2.3 (1.8 to 2.8)	2.1 (1.6 to 2.6)		

### Statistical analyses

Statistical analysis title	Non-inferiority analysis
Statistical analysis description:	
Non-inferiority analysis of rest pain NRS at 6 hours postoperatively	

A pre-specified non-inferiority analysis was performed to compare postoperative rest pain intensity between the PENG and SFIB groups at 6 hours after total hip arthroplasty. The non-inferiority margin was set at 1 numeric rating scale (NRS) point. The between-group difference was estimated using a

Mann–Whitney U test, with calculation of median difference and 95% confidence interval. Non-inferiority was concluded if the upper

Comparison groups	PENG v SFIB
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.001
Method	Mann–Whitney U test

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

48 hours after surgery

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	28.0
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### Reporting groups

Reporting group title	PENG
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Reporting group description: -

Reporting group title	SFIB
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Reporting group description: -

Serious adverse events	PENG	SFIB	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	PENG	SFIB	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 51 (11.76%)	6 / 51 (11.76%)	
Gastrointestinal disorders			
Postoperative nausea or vomiting (PONV)			
subjects affected / exposed	6 / 51 (11.76%)	6 / 51 (11.76%)	
occurrences (all)	6	6	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported