Clinical trial results:
Femoral nerve inguinal approach (FNB-Cath)versus proximal femoral triangle approach (FTB-Cath) for continuous regional analgesia in active rehabilitation after
total knee arthroplasty: A prospective, randomised study

Summary

EudraCT number	2016-001519-19
Trial protocol	FR
Global end of trial date	14 December 2018

Results information

Result version number	v1 (current)
This version publication date	03 September 2022
First version publication date	03 September 2022

Trial information

Trial identification

Sponsor protocol code	CHD050-16

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02873637
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Centre Hospitalier Départemental Vendée
Sponsor organisation address	Bd Stéphane Moreau, La Roche sur Yon, France, 85923
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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 April 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 December 2018
Global end of trial reached?	Yes
Global end of trial date	14 December 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

demonstrate that the nerve block administration for analgesic purposes via an FTB-Cath results in less quadriceps weakness than via an FNB-Cath.

Protection of trial subjects:

Treated in routine care

Background therapy:

Gabapentine (Neurontin®) - night before and procedure's morning - 600 mg
Céfuroxime (Zinnat®) - 30mn to 1h before the beginning of the intervention- 1,5g (3g si BMI >30)
Acide tranexamique (Exacyl®) - 1g ()2 injections
Dexaméthasone – one time intraoperative - 8 mg IV
Paracétamol - for the duration of the hospital stay – 4g per day
Kétoprofène – day 0 to day 4 - 100 mg (2 times per day)

Oxycodone (Oxynorm® IV , Oxycontin PO) - for the duration of the hospital stay - 5 to 10 mg every 4 to 6 hours
Ondansétron – day 0 to day 1 - 1 ampoule of 4 mg IV
Enoxaparine sodique (Lovenox®) – day 1 to day 21 - 4000 U subcutaneous
Apixaban (Eliquis®) - day 1 to day 21 - 2.5 mg PO (2 times per day)
Rémifentanil - intraoperative - 0,5 à 1 µg/kg/mn
Propofol - intraoperative - 1,5 à 2 mg/kg
Desflurane - intraoperative
Atracurium - intraoperative - 0,5mg/kg

Evidence for comparator: -	
Actual start date of recruitment	17 January 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Scientific research
Long term follow-up duration	2 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 44
Worldwide total number of subjects	44
EEA total number of subjects	44

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)	6
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Inclusion period: 24 months
First inclusion: 2017/01/17
Last inclusion: 2018/09/11

Pre-assignment

Screening details:

The screening visit verifies that the patient meets the inclusion criteria. the subject give his consent for written participation after presentation by the investigator of the study, reading of the informed consent form and response of the investigator to his questions.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Blinding is respected by positioning a blinding dressing that covers the 2 catheter insertion sites. The patient cannot then visualize the catheter's location

Arms

Are arms mutually exclusive?	Yes
Arm title	Femoral triangle catheter (FTB-Cath)

Arm description:

echo-guided placement of the KTSS catheter at the junction of the thigh inserted 3 cm into the paravascular space under the sartorial suture (puncture site 14-15 cm below the inguinal ligament)

Arm type	Experimental
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	N01BB09
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

462mg

Arm title	Catheter in Femoral nerve block (FNB-Cath)

Arm description:

coupled placement with untrasound guidance and neurostimulation of the femoral KTF at the level of the inguinal fold introduced over 3 to 5 cm in contact with the nerve with search for a motor response in ascent of the patella or contraction of the vastus medialis muscle to the neurostimulation performed by the KT in place, at an intensity if possible < 1mA for a stimulation duration of 100 µs

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	N01BB09
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

462mg

Number of subjects in period 1	Femoral triangle catheter (FTB-Cath)	Catheter in Femoral nerve block (FNB-Cath)
Started	22	22
Per-operative period (H1 to H4)	22	22
Post-operative period (D1 to D4)	22	22
Month 1	22	22
Month 2	22	22
Completed	22	22

Baseline characteristics

Reporting groups	
Reporting group title	Femoral triangle catheter (FTB-Cath)
Reporting group description:	
echo-guided placement of the KTSS catheter at the junction of the thigh inserted 3 cm into the paravascular space under the sartorial suture (puncture site 14-15 cm below the inguinal ligament)	
Reporting group title	Catheter in Femoral nerve block (FNB-Cath)
Reporting group description:	
coupled placement with untrasound guidance and neurostimulation of the femoral KTF at the level of the inguinal fold introduced over 3 to 5 cm in contact with the nerve with search for a motor response in ascent of the patella or contraction of the vastus medialis muscle to the neurostimulation performed by the KT in place, at an intensity if possible < 1mA for a stimulation duration of 100 µs	

Reporting group values	Femoral triangle catheter (FTB-Cath)	Catheter in Femoral nerve block (FNB-Cath)	Total
Number of subjects	22	22	44
Age categorical			
Units: Subjects			
Adults (18-64 years)	3	3	6
From 65-84 years	19	19	38
Age continuous			
Units: years			
arithmetic mean	72.7	70.1	
standard deviation	± 6.76	± 6.4	-
Gender categorical			
Units: Subjects			
Female	8	9	17
Male	14	13	27

End points

End points reporting groups

Reporting group title	Femoral triangle catheter (FTB-Cath)
Reporting group description:	
echo-guided placement of the KTSS catheter at the junction of the thigh inserted 3 cm into the paravascular space under the sartorial suture (puncture site 14-15 cm below the inguinal ligament)	
Reporting group title	Catheter in Femoral nerve block (FNB-Cath)
Reporting group description:	
coupled placement with untrasound guidance and neurostimulation of the femoral KTF at the level of the inguinal fold introduced over 3 to 5 cm in contact with the nerve with search for a motor response in ascent of the patella or contraction of the vastus medialis muscle to the neurostimulation performed by the KT in place, at an intensity if possible < 1mA for a stimulation duration of 100 µs	

Primary: Quadriceps strength

End point title	Quadriceps strength
End point description:	
quadriceps strength assessed clinically on postoperative day (POD) 2 by the Manual Muscle Test (MMT) using a motor grading scores [Daniels and Worthingham's international clinical score (scores 0–5)].	
End point type	Primary
End point timeframe:	
postoperative day 2	

End point values	Femoral triangle catheter (FTB-Cath)	Catheter in Femoral nerve block (FNB-Cath)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	22		
Units: number	17	3		

Statistical analyses

Statistical analysis title	Quadriceps driving force
Comparison groups	Catheter in Femoral nerve block (FNB-Cath) v Femoral triangle catheter (FTB-Cath)
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Chi-squared

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From randomization (on the day of the intervention) until the patient's discharge (M2 post-operative)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups	
Reporting group title	catheter under sartorial
Reporting group description:	
echo-guided placement of a KTSS catheter at the junction of the thigh inserted 3 cm into the paravascular space under the sartorial suture (puncture site 14-15 cm below the inguinal ligament).	
Reporting group title	femoral catheter
Reporting group description:	
Coupled placement with ultrasound guidance and neurostimulation (outside the ultrasound field) of a femoral KTF at the level of the inguinal fold introduced over 3 to 5 cm in contact with the nerve with search for a motor response in ascent of the patella or contraction of the vastus medialis muscle to the neurostimulation performed by the KT in place, at an intensity if possible < 1mA for a stimulation duration of 100µs.	

Serious adverse events	catheter under sartorial	femoral catheter	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
General disorders and administration site conditions			
Impaired healing			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	catheter under sartorial	femoral catheter	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 22 (40.91%)	8 / 22 (36.36%)	
Injury, poisoning and procedural complications			

Post procedural haematoma			
subjects affected / exposed	1 / 22 (4.55%)	1 / 22 (4.55%)	
occurrences (all)	1	1	
Nervous system disorders			
Presyncope			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Sensory loss			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 22 (13.64%)	1 / 22 (4.55%)	
occurrences (all)	4	1	
General disorders and administration site conditions			
Impaired healing			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Oedema peripheral			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Pain			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal pain upper	Additional description: or constipation		
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Nausea/ vomiting			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	
occurrences (all)	2	0	
Constipation			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			

Pulmonary embolism			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 22 (4.55%)	4 / 22 (18.18%)	
occurrences (all)	1	4	
Joint effusion			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 October 2016	Modification of intraoperative patient management: Possibility of emergency analgesia: - if EVA >40, 5 ml perivicaine perivacaine - if EVA >60, additional addition of Oxynom IV
04 January 2017	addition of a secondary objective: comparison of the rate of adverse events between the 2 arms
08 December 2017	Extension of the study duration by 12 months

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported