Clinical trial results:
Fast-track rehabilitation protocol for Total Knee Arthroplasty: A Randomized Controlled Trial comparing Local Infiltration Analgesia with Femoral Nerve Block

Summary

EudraCT number	2013-001008-13
Trial protocol	NL
Global end of trial date	06 November 2015

Results information

Result version number	v1 (current)
This version publication date	11 January 2022
First version publication date	11 January 2022
Summary attachment (see zip file)	Femoral nerve catheter vs local infiltration for analgesia in fast track total knee arthroplasty: short-term and long-term outcomes (Femoral nerve catheter vs local infiltration for analgesia in fast track total knee arthroplasty.pdf)

Trial information

Trial identification

Sponsor protocol code	497

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01966263
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sint Maartenskliniek
Sponsor organisation address	Hengstdal 3, Ubbergen, Netherlands,
Public contact	Clinical Trial Information, Sint Maartenskliniek, +31 243659935, m.fenten@maartenskliniek.nl
Scientific contact	Clinical Trial Information, Sint Maartenskliniek, +31 243659935, m.fenten@maartenskliniek.nl

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	03 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 November 2015
Global end of trial reached?	Yes
Global end of trial date	06 November 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Identifying the optimal anesthesia technique for patients undergoing total knee arthroplasty according to the fast track protocol giving the best functional outcome

Protection of trial subjects:

escape medication for pain consisted of oxycodon 5 mg per os

Background therapy:

paracetamol 1000 mg q.i.d., etoricoxib 90 mg once daily, and gabapentin 600 mg b.i.d. (300 mg if age >60 yr)

Evidence for comparator: -

Actual start date of recruitment	01 June 2013
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	Netherlands: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	41
From 65 to 84 years	39
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Eligible participants were all adults aged 50-80 years with ASA physical health classification I, II or III. Patients presented with non-inflammatory knee osteoarthritis and were scheduled for fast track, primary, unilateral total knee arthroplasty under spinal anaesthesia.

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind[1]
Roles blinded	Investigator, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	group LIA

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	Infiltration

Dosage and administration details:

local infiltration of the anterior capsule with ropivacaine 0.2%, 50 ml plus epinephrine 1:200.000 and of the subcutaneous tissue with ropivacaine 0.2%, 50 ml without epinephrine.

Arm title	group FNB

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	Infiltration

Dosage and administration details:

local infiltration of the anterior capsule with ropivacaine 0.2%, 50 ml plus epinephrine 1:200.000 and of the subcutaneous tissue with ropivacaine 0.2%, 50 ml without epinephrine.

Notes:

[1] - The roles blinded appear to be inconsistent with a double blind trial.

Justification: it was not possible to completely blind the patients, for they are aware whether they receive medication through the perineural catheter or not.

Number of subjects in period 1	group LIA	group FNB
Started	40	40
directly postoperative follow-up	40	40
3 months postoperatively follow up	40	38
Completed	36	37
Not completed	4	3
Adverse event, non-fatal	-	1
Lost to follow-up	1	1
Protocol deviation	3	1

Baseline characteristics

Reporting groups	
Reporting group title	group LIA
Reporting group description: -	
Reporting group title	group FNB
Reporting group description: -	

Reporting group values	group LIA	group FNB	Total
Number of subjects	40	40	80
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	66	64	
standard deviation	± 6.3	± 6.9	-
Gender categorical Units: Subjects			
Female	23	20	43
Male	17	20	37

End points

End points reporting groups

Reporting group title	group LIA
Reporting group description: -	
Reporting group title	group FNB
Reporting group description: -	

Primary: Timed Up and Go Test

End point title	Timed Up and Go Test
End point description:	
End point type	Primary
End point timeframe:	
at 3 months and at 12 months postoperatievly	

End point values	group LIA	group FNB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	37		
Units: second				
arithmetic mean (standard deviation)	7.8 (± 1.9)	7.6 (± 1.2)		

Statistical analyses

Statistical analysis title	timed Up and Go Test
Comparison groups	group FNB v group LIA
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Regression, Linear
Parameter estimate	Mean difference (net)
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	1.1

Primary: Six Minute Walk Test

End point title	Six Minute Walk Test

End point description:

End point type	Primary

End point timeframe:

at 12 months postoperatively

End point values	group LIA	group FNB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	36		
Units: meter				
arithmetic mean (standard deviation)	489 (± 71)	505 (± 84)		

Statistical analyses

Statistical analysis title	Six Minute Walk Test
Comparison groups	group LIA v group FNB
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Regression, Linear
Parameter estimate	Mean difference (net)
Point estimate	-32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-64
upper limit	-0.4

Primary: Stair Climb Test

End point title	Stair Climb Test

End point description:

End point type	Primary

End point timeframe:

at 12 months

End point values	group LIA	group FNB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	37		
Units: second				
arithmetic mean (standard deviation)	14.3 (± 7.1)	13.8 (± 4.7)		

Statistical analyses

Statistical analysis title	Stai Climb Test
Comparison groups	group LIA v group FNB
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Regression, Linear
Parameter estimate	Mean difference (net)
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	4.5

Secondary: Pain score (NRS)

End point title	Pain score (NRS)

End point description:

End point type	Secondary

End point timeframe:
at 3 months postoperative

End point values	group LIA	group FNB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	37		
Units: dimensionless scale				
arithmetic mean (standard deviation)	1.5 (± 2.0)	1.1 (± 1.8)		

Statistical analyses

Statistical analysis title	NRS pain scores
Comparison groups	group LIA v group FNB

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Regression, Linear
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

from start of anetshesia on the day of surgery untill the last follow up visit at 12 months post operatively

Assessment type	Non-systematic

Dictionary used

Dictionary name	toetsingonline
Dictionary version	1

Reporting groups

Reporting group title	group LIA
Reporting group description: -	
Reporting group title	group FNB
Reporting group description: -	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: non serious adverse events are not recorded during the study

Serious adverse events	group LIA	group FNB	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
falling	Additional description: One falling incident was recorded. A patient in the FNB group mobilised unattended shortly after her return to the ward. The effects of spinal anaesthesia may not have been fully resolved at this time and may have contributed to the fall.		
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	group LIA	group FNB	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30236246