Clinical trial results:
The effect of the popliteal plexus block on postoperative opioid consumption, pain, muscle strength and mobilization after total knee arthroplasty
- a randomized, controlled, blinded study

Summary

EudraCT number	2021-000242-17
Trial protocol	DK
Global end of trial date	26 June 2023

Results information

Result version number	v1 (current)
This version publication date	29 August 2024
First version publication date	29 August 2024

Trial information

Trial identification

Sponsor protocol code	Protocol_PPB_TKA_14012021

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aarhus Universitet (Aarhus)
Sponsor organisation address	Falkevej 1A, Silkeborg, Denmark, 8600
Public contact	Johan Kløvgaard Sørensen, Silkeborg Regional Hospital, Elective Surgery Centre, 0045 28945356, joksoe@rm.dk
Scientific contact	Johan Kløvgaard Sørensen, Silkeborg Regional Hospital, Elective Surgery Centre, 0045 28945356, joksoe@rm.dk
Sponsor organisation name	Aarhus Universitet (Aarhus)
Sponsor organisation address	Falkevej 1A, Silkeborg, Denmark, 8600
Public contact	Charlotte Runge, Silkeborg Regional Hospital, Elective Surgery Centre, 0045 25883172, charlotte.runge@aarhus.rm.dk
Scientific contact	Charlotte Runge, Silkeborg Regional Hospital, Elective Surgery Centre, 0045 25883172, charlotte.runge@aarhus.rm.dk

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	No

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 June 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 June 2023
Global end of trial reached?	Yes
Global end of trial date	26 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

We aim to evaluate the analgesic effects of three different nerve block regimens (Popliteal Plexus Block + Femoral Triangle Block versus Femoral Triangle Block versus Adductor Canal Block) after primary unilateral total knee arthroplasty (TKA), in order to optimize pain treatment for TKA patients and minimize the use of opioids. We observe TKA patients opioid consumption and pain scores in the period of 24 hours postoperative, while testing their muscle strength and ability to mobilize.

Protection of trial subjects:

Treated in routine care.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2021
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	Denmark: 165
Worldwide total number of subjects	165
EEA total number of subjects	165

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)	34
From 65 to 84 years	127
85 years and over	4

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	165
Number of subjects completed	165

Period 1

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

Blinding implementation details:

Three experienced regional anesthesiologists and their assistants who were responsible for performing the nerve and sham blocks, were not blinded to the treatment and excluded from further patient treatment, data collection, and data handling. All patients, outcome assessors, data analysts, and other personnel involved in the patient's treatment were blinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	Popliteal plexus block

Arm description:

10 mL for Popliteal Plexus Block
including 15 mL for Femoral Triangle block

Arm type	Experimental
Investigational medicinal product name	Marcaine 0.5%
Investigational medicinal product code	09930
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

10 mL for Popliteal Plexus Block
15 mL for Femoral Triangle Block

Arm title	Femoral Triangle Block

Arm description:

15 mL for Femoral Triangle Block

Arm type	Active comparator
Investigational medicinal product name	Marcaine 0.5%
Investigational medicinal product code	09930
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

15 mL for Femoral Triangle Block

Arm title	Adductor Canal Block

Arm description:	
25 mL for Adductor Canal Block	
Arm type	Active comparator
Investigational medicinal product name	Marcaine 0.5%
Investigational medicinal product code	09930
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

25 mL for Adductor Canal Block

Number of subjects in period 1	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block
Started	55	55	55
Completed	53	53	55
Not completed	2	2	0
Consent withdrawn by subject	-	1	-
Converted to general anesthesia peroperative	2	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Popliteal plexus block
Reporting group description: 10 mL for Popliteal Plexus Block including 15 mL for Femoral Triangle block	
Reporting group title	Femoral Triangle Block
Reporting group description: 15 mL for Femoral Triangle Block	
Reporting group title	Adductor Canal Block
Reporting group description: 25 mL for Adductor Canal Block	

Reporting group values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block
Number of subjects	55	55	55
Age categorical Units: Subjects			
Above 50 years of age	55	55	55
Age continuous Units: years			
median	71	72	74
full range (min-max)	52 to 85	54 to 86	53 to 86
Gender categorical Units: Subjects			
Female	24	30	27
Male	31	25	28

Reporting group values	Total		
Number of subjects	165		
Age categorical Units: Subjects			
Above 50 years of age	165		
Age continuous Units: years			
median			
full range (min-max)	-		
Gender categorical Units: Subjects			
Female	81		
Male	84		

End points

End points reporting groups

Reporting group title	Popliteal plexus block
Reporting group description: 10 mL for Popliteal Plexus Block including 15 mL for Femoral Triangle block	
Reporting group title	Femoral Triangle Block
Reporting group description: 15 mL for Femoral Triangle Block	
Reporting group title	Adductor Canal Block
Reporting group description: 25 mL for Adductor Canal Block	

Primary: 24-hour total intravenous oxycodone consumption

End point title	24-hour total intravenous oxycodone consumption
End point description:	
End point type	Primary
End point timeframe: From end of surgery time until 24 after surgery	

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	55	
Units: mg				
median (inter-quartile range (Q1-Q3))	6 (2 to 12)	10 (8 to 16)	12 (6 to 18)	

Statistical analyses

Statistical analysis title	PPB+FTB vs. FTB
Statistical analysis description: Pairwise comparison	
Comparison groups	Popliteal plexus block v Femoral Triangle Block
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
P-value	< 0.01
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	-4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	-1

Notes:

[1] - Difference in mg Oxycodone intravenous

Statistical analysis title	PPB+FTB vs. ACB

Statistical analysis description:

Pairwise comparison

Comparison groups	Popliteal plexus block v Adductor Canal Block
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
P-value	= 0.01
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	-6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.3
upper limit	-1.3

Notes:

[2] - Difference in mg Oxycodone intravenous

Statistical analysis title	FTB vs. ACB

Statistical analysis description:

Pairwise comparison

Comparison groups	Popliteal plexus block v Adductor Canal Block v Femoral Triangle Block
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
P-value	= 0.99
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	3.1

Notes:

[3] - Difference in mg Oxycodone intravenous

Statistical analysis title	Difference between groups
Comparison groups	Popliteal plexus block v Femoral Triangle Block v Adductor Canal Block

Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.01
Method	Kruskal-wallis

Secondary: 12- hours postoperative oxycodone consymption

End point title	12- hours postoperative oxycodone consymption

End point description:

End point type	Secondary

End point timeframe:

From end-of-surgery time to 12 hours after surgery

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	55	
Units: mg				
median (inter-quartile range (Q1-Q3))	2 (0 to 6)	6 (2 to 8)	6 (2 to 8)	

Statistical analyses

Statistical analysis title	Difference between groups
Comparison groups	Adductor Canal Block v Femoral Triangle Block v Popliteal plexus block
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.01
Method	Kruskal-wallis

Secondary: MVIC plantar flexion

End point title	MVIC plantar flexion

End point description:

Postblock maximum voluntary isometric contraction (MVIC), expressed as percentage of preblock value of plantar flexion of the ankle.

End point type	Secondary

End point timeframe:

MVIC was tested before nerve block was performed and re-tested 60 minutes after nerve block. This was conducted on the day of surgery, in the preparation room before surgery.

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	55	55	
Units: Percentage				
arithmetic mean (standard deviation)	107 (± 13)	105 (± 14)	103 (± 16)	

Statistical analyses

Statistical analysis title	Difference between groups
Comparison groups	Popliteal plexus block v Femoral Triangle Block v Adductor Canal Block
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.2
Method	ANOVA

Secondary: MVIC dorsi flexion

End point title	MVIC dorsi flexion

End point description:

Postblock maximum voluntary isometric contraction (MVIC), expressed as percentage of preblock value of plantar flexion of the ankle.

End point type	Secondary

End point timeframe:

MVIC was tested before nerve block was performed and re-tested 60 minutes after nerve block. This was conducted on the day of surgery, in the preparation room before surgery.

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	55	55	
Units: Percentage				
arithmetic mean (standard deviation)	106 (± 15)	101 (± 15)	103 (± 15)	

Statistical analyses

Statistical analysis title	Difference between groups
Comparison groups	Popliteal plexus block v Femoral Triangle Block v Adductor Canal Block

Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.42
Method	ANOVA

Secondary: MVIC knee extension

End point title	MVIC knee extension

End point description:

Postblock maximum voluntary isometric contraction (MVIC), expressed as percentage of preblock value of plantar flexion of the ankle.

End point type	Secondary

End point timeframe:

MVIC was tested before nerve block was performed and re-tested 60 minutes after nerve block. This was conducted on the day of surgery, in the preparation room before surgery.

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	55	55	
Units: Percentage				
arithmetic mean (standard deviation)	90 (± 26)	93 (± 25)	94 (± 28)	

Statistical analyses

Statistical analysis title	Difference between groups
Comparison groups	Popliteal plexus block v Femoral Triangle Block v Adductor Canal Block
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.66
Method	ANOVA

Secondary: Timed up and go test

End point title	Timed up and go test

End point description:

End point type	Secondary

End point timeframe:

5 hours after end-of-surgery

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	41	43	
Units: second				
median (inter-quartile range (Q1-Q3))	30 (22 to 48)	31 (26 to 35)	32 (22 to 46)	

Statistical analyses

Statistical analysis title	Difference between groups
Comparison groups	Popliteal plexus block v Femoral Triangle Block v Adductor Canal Block
Number of subjects included in analysis	127
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.61
Method	Kruskal-wallis

Secondary: Worst pain during Timed up and go test

End point title	Worst pain during Timed up and go test
End point description:	
Pain was rated on a numeric rating scale, with 0 = no pain and 10 = worst imaginable pain	
End point type	Secondary
End point timeframe:	
Timed up and go test was performed 5 hours after end-of-surgery time	

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	41	43	
Units: Numeric rate 0-10				
median (inter-quartile range (Q1-Q3))	3 (2 to 4)	3 (3 to 4)	4 (3 to 5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Postblock MMT plantar flexion ankle

End point title	Postblock MMT plantar flexion ankle

End point description:

MMT = Manual muscle test:
3 = normal muscle activity and joint motion
2 = Joint motion only able by elimination of gravity or minimal help from an investigator
1 = muscle activity detectable but no joint motion detectable
0 = no muscle activity or joint motion detectable

End point type	Secondary

End point timeframe:

Obtained 60 minutes after nerve block, before surgery.

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	55	55	
Units: level				
number (not applicable)				
normal muscle activity and joint motion	55	55	55	
Joint motion only able by elimination of gravity o	0	0	0	
muscle activity detectable but no joint motion	0	0	0	
no muscle activity or joint motion detectable	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Postblock MMT dorsi flexion ankle

End point title	Postblock MMT dorsi flexion ankle

End point description:

MMT = Manual muscle test:
3 = normal muscle activity and joint motion
2 = Joint motion only able by elimination of gravity or minimal help from an investigator
1 = muscle activity detectable but no joint motion detectable
0 = no muscle activity or joint motion detectable

End point type	Secondary

End point timeframe:

Obtained 60 minutes after nerve block, before surgery.

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	55	55	
Units: Level				
number (not applicable)				
normal muscle activity and joint motion	55	55	55	
Joint motion only able by elimination of gravity	0	0	0	
muscle activity detectable but no joint motion	0	0	0	
no muscle activity or joint motion detectable	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Postblock MMT knee extension

End point title	Postblock MMT knee extension

End point description:

MMT = Manual muscle test:
3 = normal muscle activity and joint motion
2 = Joint motion only able by elimination of gravity or minimal help from an investigator
1 = muscle activity detectable but no joint motion detectable
0 = no muscle activity or joint motion detectable

End point type	Secondary

End point timeframe:

Obtained 60 minutes after nerve block, before surgery.

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	55	55	
Units: level				
number (not applicable)				
normal muscle activity and joint motion	54	55	54	
Joint motion only able by elimination of gravity	0	0	0	
muscle activity detectable but no joint motion	0	0	1	
no muscle activity or joint motion detectable	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Postoperative MMT plantar flexion ankle

End point title	Postoperative MMT plantar flexion ankle

End point description:

MMT = Manual muscle test:
3 = normal muscle activity and joint motion
2 = Joint motion only able by elimination of gravity or minimal help from an investigator
1 = muscle activity detectable but no joint motion detectable
0 = no muscle activity or joint motion detectable

End point type	Secondary

End point timeframe:

Obtained 5 hours after end-of-surgery time

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	55	
Units: level				
number (not applicable)				
normal muscle activity and joint motion	53	52	54	
Joint motion only able by elimination of gravity	0	0	1	
muscle activity detectable but no joint motion	0	0	0	
no muscle activity or joint motion detectable	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Postoperative MMT dorsi flexion ankle

End point title	Postoperative MMT dorsi flexion ankle

End point description:

MMT = Manual muscle test:
3 = normal muscle activity and joint motion
2 = Joint motion only able by elimination of gravity or minimal help from an investigator
1 = muscle activity detectable but no joint motion detectable
0 = no muscle activity or joint motion detectable

End point type	Secondary

End point timeframe:

Obtained 5 hours after end-of-surgery time

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	55	
Units: level				
number (not applicable)				
normal muscle activity and joint motion	53	52	54	
Joint motion only able by elimination of gravity	0	0	1	
muscle activity detectable but no joint motion	0	0	0	
no muscle activity or joint motion detectable	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Postoperative MMT knee extension

End point title	Postoperative MMT knee extension

End point description:

MMT = Manual muscle test:
3 = normal muscle activity and joint motion
2 = Joint motion only able by elimination of gravity or minimal help from an investigator
1 = muscle activity detectable but no joint motion detectable
0 = no muscle activity or joint motion detectable

End point type	Secondary

End point timeframe:

Obtained 5 hours after end-of-surgery time

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	55	
Units: level				
number (not applicable)				
normal muscle activity and joint motion	50	50	54	
Joint motion only able by elimination of gravity	1	2	0	
muscle activity detectable but no joint motion	1	0	1	
no muscle activity or joint motion detectable	1	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Postoperative Pain at rest

End point title	Postoperative Pain at rest

End point description:

Numeric rating scale
0 = no pain
10 = worst imaginable pain

End point type	Secondary

End point timeframe:

Pain scores were obtained at enrollment on the day of surgery (before block), 2, 5, 7, 20 and 24 hours after end-of-surgery time.

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	55	
Units: Numeric rating from 0 - 10	53	53	55	

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

Neither did we find any interactions between time and group at pain at rest (p=0.18)

Comparison groups	Popliteal plexus block v Femoral Triangle Block v Adductor Canal Block
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.25 [4]
Method	Mixed models analysis

Notes:

[4] - No difference between groups in pain at rest

Secondary: Postoperative pain during active knee flexion

End point title	Postoperative pain during active knee flexion

End point description:

Active knee flexion up till maximum of 90 degree flexion of the knee.
Numeric rating scale
0 = no pain
10 = worst imaginable pain

End point type	Secondary

End point timeframe:

Pain scores were obtained at enrollment on the day of surgery (before block), 2, 5, 7, 20 and 24 hours after end-of-surgery time.

End point values	Popliteal plexus block	Femoral Triangle Block	Adductor Canal Block	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	55	
Units: Numeric rating from 0-10	53	53	55	

Statistical analyses

Statistical analysis title	Difference between groups
Statistical analysis description: Neither did we find any interactions between time and group at pain during active flexion (p=0.06)	
Comparison groups	Popliteal plexus block v Femoral Triangle Block v Adductor Canal Block
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.98
Method	Mixed models analysis

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 9 April 2021 - 26 June 2023	
Assessment type	Systematic
Dictionary used	
Dictionary name	description
Dictionary version	1
Reporting groups	
Reporting group title	Popliteal Plexus Block + Femoral Triangle Block
Reporting group description: Patients allocated to a Popliteal plexus block as adjuct to a Femoral Triangle Block	
Reporting group title	Femoral Triangle Block
Reporting group description: Patients allocated to standalone femoral triangle block	
Reporting group title	Adductor canal block
Reporting group description: Patients allocated to standalone adductor canal block	

Serious adverse events	Popliteal Plexus Block + Femoral Triangle Block	Femoral Triangle Block	Adductor canal block
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 55 (5.45%)	2 / 55 (3.64%)	1 / 55 (1.82%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Postoperative impeded quadriceps muscle strength	Additional description: Causing prolonged hospitalization, as the affected patients were discharged the on postoperative day 2 instead of postoperative day 1.		
subjects affected / exposed	1 / 55 (1.82%)	1 / 55 (1.82%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	1 / 3	0 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative nausea and vomitting	Additional description: Causing prolonged hospitalization, as the affected patients were discharged the on postoperative day 2 instead of postoperative day 1.		
subjects affected / exposed	2 / 55 (3.64%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative bleeding from the incision line	Additional description: Causing prolonged hospitalization, as the affected patients were discharged the on postoperative day 2 instead of postoperative day 1.		

subjects affected / exposed	0 / 55 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0.7 %

Non-serious adverse events	Popliteal Plexus Block + Femoral Triangle Block	Femoral Triangle Block	Adductor canal block
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 55 (9.09%)	4 / 55 (7.27%)	9 / 55 (16.36%)
General disorders and administration site conditions			
Postoperative presyncope/syncope			
subjects affected / exposed	2 / 55 (3.64%)	3 / 55 (5.45%)	7 / 55 (12.73%)
occurrences (all)	12	12	12
Musculoskeletal and connective tissue disorders			
Quadriceps weakness after TKA	Additional description: Normally seen after total knee arthroplasty (TKA), but is also seen after anesthesia of the femoral nerve (femoral triangle block or adductor canal block)		
subjects affected / exposed	3 / 55 (5.45%)	1 / 55 (1.82%)	2 / 55 (3.64%)
occurrences (all)	6	6	6

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/39019501