Clinical trial results:
postoperative effect of optimal multimodal pain management supplemented with systemic single dose of Dexamethason in the first week after UKA. Low dose (8mg) or mean dose

Summary

EudraCT number	2017-003003-22
Trial protocol	DK
Global end of trial date	12 October 2021

Results information

Result version number	v1 (current)
This version publication date	19 January 2022
First version publication date	19 January 2022

Trial information

Trial identification

Sponsor protocol code	N-20170060

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Northern Ortopaedic Division
Sponsor organisation address	Barfredsvej 83, Frederikshavn, Denmark, 9900
Public contact	Frederikshavn Sygehus, Ortopedic Department, Aalborg University Hospital, +45 22851102, m.brouw@rn.dk
Scientific contact	Frederikshavn Sygehus, Ortopedic Department, Aalborg University Hospital, +45 22851102, m.brouw@rn.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 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 October 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 October 2021
Global end of trial reached?	Yes
Global end of trial date	12 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Pain management i the first week after UKA

Protection of trial subjects:

All subjects had acess to escape pain-killers

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2018
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: 90
Worldwide total number of subjects	90
EEA total number of subjects	90

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)	44
From 65 to 84 years	46
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment period: 01.01.2018 till 01.10.2019.
North Jutland Region, Denmark

Pre-assignment

Screening details:

Recruitment period: 01.01.2018 till 01.10.2019.
North Jutland Region, Denmark.
Patients referred from GP to hospital with knee pains were screened. Patients without need for surgical interventions were excluded.

Period 1

Period 1 title	Study period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

No blinding

Arms

Are arms mutually exclusive?	Yes
Arm title	8 mg

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Injection

Dosage and administration details:

8 mg dexamethasone administered I.V. immediately before surgery.

Arm title	16 mg

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Injection

Dosage and administration details:

16 mg dexamethasone administered I.V. immediately before surgery.

Arm title	24 mg

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Injection

Dosage and administration details:
24 mg dexamethasone administered I.V. immediately before surgery.

Number of subjects in period 1	8 mg	16 mg	24 mg
Started	34	35	21
Completed	34	35	21

Baseline characteristics

Reporting groups	
Reporting group title	8 mg
Reporting group description: -	
Reporting group title	16 mg
Reporting group description: -	
Reporting group title	24 mg
Reporting group description: -	

Reporting group values	8 mg	16 mg	24 mg
Number of subjects	34	35	21
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	18	18	8
From 65-84 years	16	17	13
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	14	19	6
Male	20	16	15

Reporting group values	Total		
Number of subjects	90		
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)	44		
From 65-84 years	46		
85 years and over	0		
Gender categorical Units: Subjects			
Female	39		
Male	51		

End points

End points reporting groups	
Reporting group title	8 mg
Reporting group description: -	
Reporting group title	16 mg
Reporting group description: -	
Reporting group title	24 mg
Reporting group description: -	

Primary: Mean NRS pain 2 days post Surgery	
End point title	Mean NRS pain 2 days post Surgery
End point description: Mean NRS pain in activity	
End point type	Primary
End point timeframe: 2 days after surgery	

End point values	8 mg	16 mg	24 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	35	21	
Units: NRS				
median (standard deviation)	4.264706 (± 1.420622)	4.257143 (± 1.380328)	4.333333 (± 1.583647)	

Attachments (see zip file)	Mean NRS during activity/Mean NRS during activity.pdf

Statistical analyses	
Statistical analysis title	Kruskal-Wallis equality-of-populations rank test
Statistical analysis description: Mean NRS pain during activity	
Comparison groups	8 mg v 16 mg v 24 mg
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	≤ 0.05
Method	Kruskal-wallis

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 01-01-2018 til 12-10-2021	
Assessment type	Systematic

Dictionary used	
Dictionary name	GCP unit
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

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: We did not record any adverse events.

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