Clinical trial results:
Effect of high versus low dose intravenous dexamethason on complications in the immediate postoperative setting after periacetabular osteotomy- a randomized, double-blind, controlled trial.

Summary

EudraCT number	2017-000544-17
Trial protocol	DK
Global end of trial date	20 September 2019

Results information

Result version number	v1 (current)
This version publication date	19 April 2020
First version publication date	19 April 2020

Trial information

Trial identification

Sponsor protocol code	DEXGANZ01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03161938
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eske K Aasvang
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark, 2100
Public contact	Kristin Julia Steinthorsdottir, Rigshospitalet, 0045 31666112, kjs@dadlnet.dk
Scientific contact	Kristin Julia Steinthorsdottir, Rigshospitalet, 31666112 31666112, kjs@dadlnet.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	03 February 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 September 2019
Global end of trial reached?	Yes
Global end of trial date	20 September 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effects of high versus low dose glucorticoids on pain after periacetabular osteotomy

Protection of trial subjects:

All trial subjects underwent standard procedures, only difference was the dosage of dexamethasone

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2017
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: 64
Worldwide total number of subjects	64
EEA total number of subjects	64

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)	64
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Denmark, 1/5-2017 to 20/8-2019

Pre-assignment

Screening details:

Eligible patients are informed about the trial in relation to the pre-operative appointment. Enrolled participants are randomized and assigned to consecutive numbers (1-64) at the morning of surgery.
Inclusion criteria

- Planned PAO
- Age 18 years or older
- Able to understand Danish or English and to provide informed oral and written consent

Period 1

Period 1 title	overall (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

Arms

Are arms mutually exclusive?	Yes
Arm title	48 mg dexamethasone

Arm description:

48 mg dexamethasone

Arm type	Experimental
Investigational medicinal product name	dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

single-dose intravenous

Arm title	8 mg dexamethasone

Arm description:

8 mg dexamethasone

Arm type	Active comparator
Investigational medicinal product name	dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

single-dose intravenous

Number of subjects in period 1	48 mg dexamethasone	8 mg dexamethasone
Started	32	32
Completed	32	32

Baseline characteristics

Reporting groups	
Reporting group title	overall

Reporting group description: -

Reporting group values	overall	Total	
Number of subjects	64	64	
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	29		
standard deviation	± 8	-	
Gender categorical Units: Subjects			
Female	51	51	
Male	13	13	

End points

End points reporting groups	
Reporting group title	48 mg dexamethasone
Reporting group description: 48 mg dexamethasone	
Reporting group title	8 mg dexamethasone
Reporting group description: 8 mg dexamethasone	

Primary: Pain in the PACU	
End point title	Pain in the PACU
End point description: The primary endpoint was the proportion of patients reporting moderate to severe pain at rest (>3 out of 10 on a Numeric Rating Scale from 0-10 (NRS)) in the immediate postoperative phase (after extubation in the operating room, and in the PACU until transfer to the ward).	
End point type	Primary
End point timeframe: 12 hours	

End point values	48 mg dexamethasone	8 mg dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	32		
Units: participants	26	22		

Statistical analyses

Statistical analysis title	primary outcome fischers
Comparison groups	48 mg dexamethasone v 8 mg dexamethasone
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.248
Method	Chi-squared corrected
Parameter estimate	Odds ratio (OR)
Point estimate	0.508
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.159
upper limit	1.62

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 60 hours after administration of trial drug	
Assessment type	Systematic

Dictionary used	
Dictionary name	SNOMED CT
Dictionary version	10

Reporting groups	
Reporting group title	48 mg dexamethasone
Reporting group description: 48 mg dexamethasone	
Reporting group title	8 mg dexamethasone
Reporting group description: 8 mg dexamethasone	

Serious adverse events	48 mg dexamethasone	8 mg dexamethasone	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 32 (3.13%)	0 / 32 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Surgical and medical procedures			
Arterial injury	Additional description: gluteal artery damage, iatrogenic intraoperative		
subjects affected / exposed	1 / 32 (3.13%)	0 / 32 (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	48 mg dexamethasone	8 mg dexamethasone	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 32 (21.88%)	4 / 32 (12.50%)	
Ear and labyrinth disorders			
Dizziness postural	Additional description: dizziness at mobilization		
subjects affected / exposed	7 / 32 (21.88%)	4 / 32 (12.50%)	
occurrences (all)	7	4	

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