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

Summary

EudraCT number	2017-000505-20
Trial protocol	DK
Global end of trial date	03 December 2018

Results information

Result version number	v1 (current)
This version publication date	29 February 2020
First version publication date	29 February 2020

Trial information

Trial identification

Sponsor protocol code	DEXNEF01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Eske K Aasvang
Sponsor organisation address	blegdamsvej 9, copenhagen, Denmark,
Public contact	Kristin Julia Steinthorsdottir, Rigshospitalet, 0045 31666112, kristin.julia.steinthorsdottir.01@regionh.dk
Scientific contact	Kristin Julia Steinthorsdottir, Rigshospitalet, 0045 31666112, kristin.julia.steinthorsdottir.01@regionh.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	20 February 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 December 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of high versus low dose intravenous dexamethasone on complications in the immediate postoperative setting after nephrectomy, heminephrectomy. Main objective complications demanding treatment in the post anaesthesia care unit (PACU) (pain, nausea).

Protection of trial subjects:

Trial subjects followed standard procedures. There was no extra distress or discomfort related to the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 April 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: 41
Worldwide total number of subjects	41
EEA total number of subjects	41

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)	19
From 65 to 84 years	21
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

at preoperative appointment

Pre-assignment

Screening details:

lægelig vurdering

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	8 mg dexamethasone

Arm description: -

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

Dosage and administration details:

8 mg iv bolus

Arm title	24 mg dexamethasone

Arm description: -

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

Dosage and administration details:

24 mg iv bolus

Number of subjects in period 1	8 mg dexamethasone	24 mg dexamethasone
Started	19	22
Completed	19	22

Baseline characteristics

Reporting groups	
Reporting group title	overall

Reporting group description: -

Reporting group values	overall	Total	
Number of subjects	41	41	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	18	18	
From 65-84 years	22	22	
85 years and over	1	1	
all	0	0	
Age continuous Units: years			
median	67		
inter-quartile range (Q1-Q3)	58 to 74	-	
Gender categorical Units: Subjects			
Female	10	10	
Male	31	31	
height Units: cm			
arithmetic mean	178		
standard deviation	± 8	-	
weight Units: kg			
arithmetic mean	89		
standard deviation	± 18	-	

End points

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

Primary: Primary endpoint	
End point title	Primary endpoint
End point description: Any complications (YES/NO) in the post-anesthesia care unit	
End point type	Primary
End point timeframe: hours	

End point values	8 mg dexamethasone	24 mg dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	22		
Units: patients				
YES	13	18		
NO	6	2		
missing	0	2		

Statistical analyses

Statistical analysis title	chi-square test
Comparison groups	8 mg dexamethasone v 24 mg dexamethasone
Number of subjects included in analysis	41
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.127
Method	Chi-squared corrected
Parameter estimate	Odds ratio (OR)
Point estimate	0.241
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.042
upper limit	1.388

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 60 hours from administration of study drug	
Assessment type	Systematic

Dictionary used	
Dictionary name	non used (no AE)
Dictionary version	0

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

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: There were no non-serious adverse events recorded withj a frequency>5%

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The trial was ended prematurely due to recruitment problems. Therefore only primary endpoint is reported. There were no differences between groups.

Notes: