Clinical trial results:
Preoperativ dexamethasone for patients undergoing laparoscopy for suspected appendicitis.

Summary

EudraCT number	2014-005040-18
Trial protocol	DK
Global end of trial date	23 October 2015

Results information

Result version number	v1 (current)
This version publication date	22 November 2017
First version publication date	22 November 2017

Trial information

Trial identification

Sponsor protocol code	2014-707

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Nordsjællands Hospital
Sponsor organisation address	Dyrehavevej 29, Hillerød, Denmark, 3400
Public contact	Jakob Kleif, Kirurgisk afdeling, Nordsjællands Hospital, +45 48292005, jakob.kleif@regionh.dk
Scientific contact	Jakob Kleif, Kirurgisk afdeling, Nordsjællands Hospital, +45 48292005, jakob.kleif@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	26 October 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 October 2015
Global end of trial reached?	Yes
Global end of trial date	23 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To test whether preoperative dexamethason can reduce postoperativ nausea and vomiting and enhance postoperativ recovery after a laparoscopy for suspected appendicitis.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2015
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: 119
Worldwide total number of subjects	119
EEA total number of subjects	119

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)	105
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment between 30.04.2015 to 02.09.2016

Pre-assignment

Screening details:

170 patients screenet by attending surgeon. 120 allocated, one patient withdrew consent prior to receiving intervention. 119 patients included.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

2 ml Saline

Arm title	Dexamethasone
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

2 ml Dexamethasone 4mg/ml

Number of subjects in period 1	Placebo	Dexamethasone
Started	60	59
Completed	59	57
Not completed	1	2
Consent withdrawn by subject	1	1
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Dexamethasone
Reporting group description: -	

Reporting group values	Placebo	Dexamethasone	Total
Number of subjects	60	59	119
Age categorical Units: Subjects			
Adults (>17 years)			0
Age continuous Units: years			
median	38	41	
inter-quartile range (Q1-Q3)	24 to 53	27 to 57	-
Gender categorical Units: Subjects			
Female	36	27	63
Male	24	32	56

End points

End points reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Dexamethasone
Reporting group description: -	

Primary: PONV	
End point title	PONV
End point description: Postoperative nausea or vomiting.	
End point type	Primary
End point timeframe: During first postoperative day	

End point values	Placebo	Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	57		
Units: Patients	37	27		

Statistical analyses

Statistical analysis title	PONV
Statistical analysis description: Logistic regression	
Comparison groups	Dexamethasone v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	33

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 30 days postoperative	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Reporting groups	
Reporting group title	Dexamethasone
Reporting group description: -	
Reporting group title	Placebo (saline)
Reporting group description: 30 days postoperative	

Serious adverse events	Dexamethasone	Placebo (saline)	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 59 (10.17%)	5 / 60 (8.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
General disorders and administration site conditions			
Others			
subjects affected / exposed	6 / 59 (10.17%)	5 / 60 (8.33%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Dexamethasone	Placebo (saline)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 59 (28.81%)	20 / 60 (33.33%)	
General disorders and administration site conditions			
Others			
subjects affected / exposed	17 / 59 (28.81%)	20 / 60 (33.33%)	
occurrences (all)	17	20	

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