Clinical trial results:
Preoperative methylprednisolone to patients suspected of appendicitis undergoing laparoscopy.

Summary

EudraCT number	2015-004800-46
Trial protocol	DK
Global end of trial date	23 September 2016

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	2015-810

Additional study identifiers

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

Notes:

Sponsors

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

Notes:

General information about the trial

Main objective of the trial:

To test whether preoperative methylprednisolone can reduce postoperative pain after laparoscopy for suspected appendicitis.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 January 2016
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: 78
Worldwide total number of subjects	78
EEA total number of subjects	78

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)	72
From 65 to 84 years	5
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

From 12.04.2016 to 24.08.2016 127 were eligible, 78 patients were included and randomised.

Pre-assignment

Screening details:

Screen by attending surgeon.

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	Methylprednisolone

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Methylprednisolone
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:

125 mg (2 ml) Methylprednisolone.

Number of subjects in period 1	Placebo	Methylprednisolone
Started	40	38
Completed	40	38

Baseline characteristics

End points

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

Primary: Pain during the first 3 postoperative days	
End point title	Pain during the first 3 postoperative days
End point description:	
The analysis was made using repeated measures. Therefore the mean for each study group is not reported. (Written as zero because the system needs a value).	
End point type	Primary
End point timeframe:	
3 first postoperative days	

End point values	Placebo	Methylprednisolone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	38		
Units: VAS				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)		

Statistical analyses

Statistical analysis title	Difference in Pain the first 3 postoperative days
Comparison groups	Placebo v Methylprednisolone
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.571
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.9

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 30 days postoperative.	
Assessment type	Systematic
Dictionary used	
Dictionary name	Clavien-dindo
Dictionary version	1
Reporting groups	
Reporting group title	Placebo (saline)
Reporting group description: -	
Reporting group title	Methylprednisolon
Reporting group description: -	

Serious adverse events	Placebo (saline)	Methylprednisolon	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 40 (12.50%)	2 / 38 (5.26%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
General disorders and administration site conditions			
Other			
subjects affected / exposed	5 / 40 (12.50%)	2 / 38 (5.26%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo (saline)	Methylprednisolon	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 40 (27.50%)	9 / 38 (23.68%)	
General disorders and administration site conditions			
Other			
subjects affected / exposed	11 / 40 (27.50%)	9 / 38 (23.68%)	
occurrences (all)	11	9	

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