



Clinical trial results: PreOperative Steroid in Abdominal Wall Reconstruction: A Double-blinded Randomized Clinical Trial

Summary

EudraCT number	2015-004916-39
Trial protocol	DK
Global end of trial date	30 May 2018

Results information

Result version number	v1 (current)
This version publication date	14 February 2021
First version publication date	14 February 2021
Summary attachment (see zip file)	Final publication (Study_5.pdf)

Trial information

Trial identification

Sponsor protocol code	2015-806
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02594241
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bispebjerg Hospital
Sponsor organisation address	Bispebjerg Bakke 23, Copenhagen NV, Denmark, 2400
Public contact	Clinical trial information, Kristian Kiim Jensen, +45 35312201, kristian.kiim.jensen@regionh.dk
Scientific contact	Clinical trial information, Kristian Kiim Jensen, +45 35312201, kristian.kiim.jensen@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	03 June 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 May 2018
Global end of trial reached?	Yes
Global end of trial date	30 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To examine the effects of methylprednisolone on postoperative pain after giant ventral hernia repair.

Protection of trial subjects:

Patients were treated according to the standards of care for patients undergoing surgery for large ventral hernia.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 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: 42
Worldwide total number of subjects	42
EEA total number of subjects	42

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)	20
From 65 to 84 years	21
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

All patients were included at the Digestive Disease Center, Bispebjerg Hospital from March 1 2016 to May 1 2018.

Pre-assignment

Screening details:

All patients scheduled for undergoing surgical repair of a large incisional hernia at the Digestive Disease Center, Bispebjerg Hospital were screened.

Period 1

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

Blinding implementation details:

An independent physician performed the randomization using a computer-generated sequence with varying block sizes, involving preparing sealed envelopes. Based on randomization, another physician not otherwise involved in the study prepared either the study medication or the placebo and administered it to the patient during induction of anesthesia. Patients, data collectors, and medical staff involved in the treatment of patients were blinded to the study allocation.

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention

Arm description:

The intervention arm of the trial.

Arm type	Experimental
Investigational medicinal product name	Solu-medrol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

125 mg Solu-medrol.

Arm title	Placebo
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Arm description:

The placebo arm of the trial

Arm type	Placebo
Investigational medicinal product name	154 mM NaCl
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

154 mM NaCl.

Number of subjects in period 1	Intervention	Placebo
Started	21	21
Completed	20	20
Not completed	1	1
Consent withdrawn by subject	1	1

Baseline characteristics

Reporting groups

Reporting group title	Overall period
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Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	42	42	
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)	20	20	
From 65-84 years	21	21	
85 years and over	1	1	
Gender categorical			
Units: Subjects			
Female	18	18	
Male	24	24	

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description: The intervention arm of the trial.	
Reporting group title	Placebo
Reporting group description: The placebo arm of the trial	
Subject analysis set title	Final analysis
Subject analysis set type	Per protocol
Subject analysis set description: The analysis of patients who completed the trial	

Primary: Pain at rest during the first five postoperative days

End point title	Pain at rest during the first five postoperative days
End point description:	
End point type	Primary
End point timeframe: First five postoperative days.	

End point values	Intervention	Placebo	Final analysis	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	20	20	40	
Units: NRS				
arithmetic mean (standard deviation)	1.4 ($\pm$ 1.9)	1.6 ($\pm$ 1.8)	1.5 ($\pm$ 1.8)	

Statistical analyses

Statistical analysis title	Overall analysis of pain during first five days
Statistical analysis description: Repeated measurement, mixed effect regression, as a Wald test for overall differences between the 2 groups.	
Comparison groups	Intervention v Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis

Adverse events

Adverse events information

Timeframe for reporting adverse events:

30 days postoperatively

Adverse event reporting additional description:

All adverse events reported according to the GCP guidelines.

Assessment type	Systematic
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Dictionary used

Dictionary name	SNOMED CT
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Dictionary version	18
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Reporting groups

Reporting group title	Intervention
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Reporting group description:

Group of patients receiving the intervention.

Reporting group title	Placebo
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Reporting group description:

Group receiving placebo

Serious adverse events	Intervention	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 21 (19.05%)	1 / 21 (4.76%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Cardiac arrest	Additional description: Patient had malignant hyperthermia and cardiac arrest during surgery. Patient was resuscitated immediately and recovered fully.		
subjects affected / exposed	1 / 21 (4.76%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Readmission	Additional description: Patients readmitted due to pain from the surgical site, vomiting or gastroenteritis.		
subjects affected / exposed	4 / 21 (19.05%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Intervention	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 21 (4.76%)	2 / 21 (9.52%)	
Skin and subcutaneous tissue disorders			
Skin irritation	Additional description: Minor itching one postoperative day one.		
subjects affected / exposed	1 / 21 (4.76%)	2 / 21 (9.52%)	
occurrences (all)	1	2	

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.

None.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/32061400>