



Clinical trial results:

The effect of Phrenic nerve blockade on acute and chronic shoulder pain in patients for lobectomy and pneumonectomy.

Summary

EudraCT number	2012-002844-25
Trial protocol	DK
Global end of trial date	01 July 2015

Results information

Result version number	v1 (current)
This version publication date	26 July 2021
First version publication date	26 July 2021
Summary attachment (see zip file)	Summary of results (Summary of results EudraCT.pdf)

Trial information

Trial identification

Sponsor protocol code	12.006
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	J.B.Winsloews Vej 4, Odense, Denmark, 5000
Public contact	Morten Rune Blichfeldt-Eckhardt, Morten Rune Blichfeldt-Eckhardt, +45 65412528, morten.rune.blichfeldt-eckhardt@ouh.regionsyddanmark.dk
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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	08 May 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 June 2014
Global end of trial reached?	Yes
Global end of trial date	01 July 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To test whether blockade of the phrenic nerve can reduce postoperative shoulder pain after lobectomy and pneumonectomy.

Protection of trial subjects:

Patients were given the optimal treatment before, under and after the procedures

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 September 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects**Subjects enrolled per country**

Country: Number of subjects enrolled	Denmark: 76
Worldwide total number of subjects	76
EEA total number of subjects	76

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)	27
From 65 to 84 years	48
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Recruitment period: November 2012 - June 2014.

Recruitment place: Odense University Hospital, Denmark

Pre-assignment

Screening details:

screening criteria: scheduled for elective lobectomy or pneumonectomy for non-small cell lung cancer, aged > 18 y, appropriate Danish language skills to complete the pre-operative questionnaire.

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	intervention

Arm description:

Participants receive phrenic nerve block with Ropivacaine

Arm type	Experimental
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Injection

Dosage and administration details:

Ropivacaine 10mg/ml

Arm title	Placebo
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Arm description:

Received a phrenic nerve block with Saline

Arm type	Placebo
Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

Saline 0.9%

Number of subjects in period 1	intervention	Placebo
Started	38	38
Completed	38	38

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	76	76	
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)	27	27	
From 65-84 years	48	48	
85 years and over	1	1	
Adults	0	0	
Gender categorical			
Units: Subjects			
Female	44	44	
Male	32	32	

End points

End points reporting groups

Reporting group title	intervention
Reporting group description:	
Participants receive phrenic nerve block with Ropivacaine	
Reporting group title	Placebo
Reporting group description:	
Recieved a phrenic nerve block with Saline	
Subject analysis set title	Primary endpoint
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants in the study, analysed for the primary end point	

Primary: Ipsilateral shoulder pain within 6 hours after surgery.

End point title	Ipsilateral shoulder pain within 6 hours after surgery.
End point description:	
End point type	Primary
End point timeframe:	
6 hours after surgery	

End point values	intervention	Placebo	Primary endpoint	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	38	38	76	
Units: number of participants				
Participants with shoulder pain	9	26	35	
Participants without shoulder pain	29	12	41	

Statistical analyses

Statistical analysis title	Chi squared test
Comparison groups	intervention v Placebo
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.00001
Method	Chi-squared
Parameter estimate	Relatie risk reduction
Point estimate	0.65

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	0.8

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During hospitalization, first week after dismission and at the 1 year follow up.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.1
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Reporting groups

Reporting group title	Intervention
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	Intervention	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 38 (0.00%)	0 / 38 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Intervention	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 38 (15.79%)	0 / 38 (0.00%)	
Musculoskeletal and connective tissue disorders			
Motor block of arm	Additional description: Motorical blockade of the ipsilateral arm		
subjects affected / exposed	6 / 38 (15.79%)	0 / 38 (0.00%)	
occurrences (all)	15	0	

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