Clinical trial results:
Bronchoscopic indocyanine green fluorescence imaging for the evaluation of tracheal perfusion after surgery

Summary

EudraCT number	2013-001725-10
Trial protocol	AT
Global end of trial date	01 August 2016

Results information

Result version number	v1 (current)
This version publication date	24 September 2020
First version publication date	24 September 2020
Summary attachment (see zip file)	Publication_ATS (Bronchoscopic Indocyanine Green Fluorescence Imaging of the Anastomotic Perfusion After Tracheal Surgery.pdf)

Trial information

Trial identification

Sponsor protocol code	13-001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Wien
Sponsor organisation address	Spitalgasse 23, Vienna, Austria,
Public contact	Department für Chirurgie, Medizinische Universität Wien, 0043 1404006979, konrad.hoetzenecker@meduniwien.ac.at
Scientific contact	Department für Chirurgie, Medizinische Universität Wien, 0043 1404006979, konrad.hoetzenecker@meduniwien.ac.at

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	01 August 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 July 2015
Global end of trial reached?	Yes
Global end of trial date	01 August 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Anastomotic complications state a serious problem in tracheal surgery. However, conventional bronchoscopy is the only available modality to directly observe the perfusion of the anastomotic site. Aim of this study is to show that the procedure of ICG bronchoscopy is feasible. In the future, ICG bronchoscopy might help to identify patients with impaired perfusion at the anastomotic site earlier and guide the surgeon in the further management of such patients.

Protection of trial subjects:

Contraindications for the application of ICG have to be exluded in advance. The patients will be observed for at least 1.5 hours after application for any acute drug-related AE. The obtained data will be stored anonymized and locked.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 November 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	7
From 65 to 84 years	5

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All patients receiving elective laryngotracheal surgery at the Division of Thoracic Surgery, Medical University Vienna and patients

Pre-assignment

Screening details:

-informed-consent to participate
-exclusion of allergy to iodide

Period 1

Period 1 title	Measurements (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Open-label feasibility

Arms

Arm title	Feasibility

Arm description:

Feasibility of ICG bronchoscopy

Arm type	Experimental
Investigational medicinal product name	INDOCYANINE GREEN
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

0.3mg per kg bodyweight via a peripheral venous catheter

Number of subjects in period 1	Feasibility
Started	12
Completed	12

Baseline characteristics

Reporting groups	
Reporting group title	Measurements
Reporting group description: -	

Reporting group values	Measurements	Total	
Number of subjects	12	12	
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)	7	7	
From 65-84 years	5	5	
85 years and over	0	0	
Age continuous Units: years			
median	57		
full range (min-max)	29 to 75	-	
Gender categorical Units: Subjects			
Female	5	5	
Male	7	7	

Subject analysis sets	
Subject analysis set title	Final analysis
Subject analysis set type	Full analysis
Subject analysis set description: Final analysis of all patients (n=12)	
Subject analysis set title	Measurement intra-op
Subject analysis set type	Sub-group analysis
Subject analysis set description: Performed intraoperative measurements	
Subject analysis set title	Measurement before hospital discharge
Subject analysis set type	Sub-group analysis
Subject analysis set description: Performed measurements before hospital discharge	
Subject analysis set title	Follow-up
Subject analysis set type	Sub-group analysis
Subject analysis set description: Final measurement 2 months after surgery	

Reporting group values	Final analysis	Measurement intra-op	Measurement before hospital discharge
Number of subjects	12	11	11
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	7	6	6
From 65-84 years	5	5	5
85 years and over	0	0	0
Age continuous			
Units: years			
median	57	61	61
full range (min-max)	29 to 75	29 to 75	29 to 75
Gender categorical			
Units: Subjects			
Female	5		
Male	7		

Reporting group values	Follow-up		
Number of subjects	10		
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)	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)	7		
From 65-84 years	3		
85 years and over	0		
Age continuous			
Units: years			
median	51		
full range (min-max)	29 to 74		
Gender categorical			
Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Feasibility
Reporting group description: Feasibility of ICG bronchoscopy	
Subject analysis set title	Final analysis
Subject analysis set type	Full analysis
Subject analysis set description: Final analysis of all patients (n=12)	
Subject analysis set title	Measurement intra-op
Subject analysis set type	Sub-group analysis
Subject analysis set description: Performed intraoperative measurements	
Subject analysis set title	Measurement before hospital discharge
Subject analysis set type	Sub-group analysis
Subject analysis set description: Performed measurements before hospital discharge	
Subject analysis set title	Follow-up
Subject analysis set type	Sub-group analysis
Subject analysis set description: Final measurement 2 months after surgery	

Primary: Successful visualization of ICG flourescence

End point title	Successful visualization of ICG flourescence[1]
End point description:	
End point type	Primary
End point timeframe: Immediately after ICG injection	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Feasibilty study. Please see attached publication.

End point values	Final analysis			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: ICG fluorescence signal	12			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Time from surgery until last follow-up	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups	
Reporting group title	Feasibility
Reporting group description:	
Feasibility of ICG bronchoscopy	

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: In this trial with a rather limited number of patients, no non-serious adverse-event occured. One patient died during follow-up due to sudden cardiac death (as listed in the serious adverse event section).

Serious adverse events	Feasibility		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Sudden cardiac death at home	Additional description: Found dead at home two months after last study-related procedure/surgery. Previously known atrial fibrillation.		
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

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

Non-serious adverse events	Feasibility		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		

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