Clinical trial results:
Minimizing contrast agent in computed tomography pulmonary angiography

Summary

EudraCT number	2015-004657-40
Trial protocol	SE
Global end of trial date	01 May 2020

Results information

Result version number	v1 (current)
This version publication date	02 December 2021
First version publication date	02 December 2021
Summary attachment (see zip file)	CTPA2015 report abstract (200630_CTPA2015_abstract.pdf)

Trial information

Trial identification

Sponsor protocol code	CTPA-2015

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Region Örebro län
Sponsor organisation address	Universitetssjukhuset Örebro, Örebro, Sweden,
Public contact	Mats Lidén, Region Örebro län, +46 196020370, mats.liden@regionorebrolan.se
Scientific contact	Mats Lidén, Region Örebro län, +46 196020370, mats.liden@regionorebrolan.se

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	05 March 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 May 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To develop and evaluate a computed tomography protocol for ruling out pulmonary embolism using a minimal amount of contrast medium.

Protection of trial subjects:

All contrast media utilization for subjects in the study followed national and European guidelines for use of iodinated contrast media in computed tomography.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 September 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	Sweden: 55
Worldwide total number of subjects	55
EEA total number of subjects	55

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)	14
From 65 to 84 years	40
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients with planned contrast media enhanced chest CT at the study site were screened for participation and 55 participants were included in this single arm study.

Period 1

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

Arms

Arm title	Single arm

Arm description:

Development and evaluation of contrast media protocol

Arm type	Experimental
Investigational medicinal product name	Omnipaque
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

Single dosage corresponding to up to 80 mg iodine/ kg body weight. Maximum total dosage in study was 20 mL Omnipaque 350 mg/mL.

Number of subjects in period 1	Single arm
Started	55
Completed	55

Baseline characteristics

Reporting groups	
Reporting group title	Overall

Reporting group description: -

Reporting group values	Overall	Total	
Number of subjects	55	55	
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)	14	14	
From 65-84 years	40	40	
85 years and over	1	1	
Gender categorical Units: Subjects			
Female	30	30	
Male	25	25	

End points

End points reporting groups

Reporting group title	Single arm
Reporting group description:	
Development and evaluation of contrast media protocol	

Primary: Image quality

End point title	Image quality[1]
End point description:	
Subjective image quality considering pulmonary embolism.	
End point type	Primary
End point timeframe:	
The image quality was independently assessed by three blinded readers in a separate reading.	

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: The statistical analysis was the proportion of images with at least adequate image quality, with no comparison groups.

End point values	Single arm			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: numbers				
Good-excellent	44			
Adequate	3			
Non-diagnostic	0			
Not evaluated	8			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Any acute adverse events following contrast media administration were identified before the participant left the radiology department.

Assessment type	Systematic

Dictionary used

Dictionary name	Not used
Dictionary version	0

Reporting groups

Reporting group title	Overall

Reporting group description: -

Serious adverse events	Overall		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 55 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Overall		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 55 (0.00%)		

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: There were no adverse events encountered.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 March 2017	Change in inclusion criteria.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32436788