



Clinical trial results: *Full title of Trial**

The use of Contrast Enhanced Transesophageal Echocardiography in thoracic endovascular aortic repair (TEVAR). Feasibility and safety of a new tool for intraoperative monitoring and follow up.

Summary

EudraCT number*	2010-018767-42
Trial protocol	
Global end of trial date*	MARCH 2014

Trial information

Trial identification

Sponsor protocol code*	CEUS-TEVAR-29 - 1 - 19-10-2009
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Additional study identifiers

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

Notes:

Sponsors details*

Sponsor organisation name	IRCCS Ospedale San Raffaele
Sponsor organisation address	Via Olgettina, 60, Milano, Italy, 20132
Public contact	
Scientific contact	

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?	NOT APPLICABLE
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	NOT APPLICABLE

Results analysis stage

Analysis stage*	Final
Date of interim/final analysis*	
Is this the analysis of the primary completion data?*	Yes
Global end of trial reached?*	Yes
Global end of trial date*	3.2014
Was the trial ended prematurely?	No

General information about the trial

Main objective of the trial*: The aim of this study is to assess the possible role of contrast-enhanced Transesophageal echocardiography in the operator room and evaluate its diagnostic accuracy in early endoleak detection, compared to Transesophageal echocardiography alone. The secondary objective is to identify the diagnostic accuracy of contrast-enhanced Transesophageal echocardiography in the follow up of patients who previously underwent TEVAR.

Actual start date of recruitment*	2/2009
Long term follow-up planned*	No
If Yes, rationale:	Safety Efficacy Ethical reason Regulatory reason Scientific research
Duration	Months - Years
Independent data monitoring committee (IDMC) involvement?*	No
Protection of trial subjects*:	
Background therapy:	No changes despite the therapy
Evidence for comparator:	Angiography

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

Country:	
Planned number of subjects	50
Actual Number of subjects enrolled*	54
Worldwide total number of subjects	NONE
EEA total number of subjects	43

Subjects enrolled per age group

In utero*	NONE
Preterm newborn - gestational age < 37wks*	NONE
Newborns (0-27 days)*	NONE
Infants and toddlers (28 days-23months)*	NONE
Children (2-11 years)*	NONE
Adolescents (12-17 years)*	NONE
Adults (18-64 years)*	8
From 65 to 84 years*	45
85 years and over*	1

Subject disposition

Recruitment details: patients eligible for endovascular treatment of descending thoracic aorta diseases. Patient will be already known for type 2 aortic dissection, for aortic penetrating ulcer, for aneurysms of descending thoracic aorta.

Pre-assignment - Screening details: Standard practice of TEVAR mandates the study of the aortic disease with a helical contrast enhanced CT scan (32 – 64 detectors). CT allows the study and the definition of a variety of details that are important for the procedure. In particular it permits to evaluate aortic diameters, the presence of a suitable proximal and distal neck, aortic conformation with regard to the arch angulation, the need for additional open or endovascular procedures.

Period 1

Period title*	OVERALL TRIAL
Is this the baseline period?	Yes
Allocation method*	Not applicable
Blinding used*	Not blinded

Arms

Arm title*	<i>Active comparator to gold standard</i>
Arm description:	<i>Contrast enhanced toe before angiography</i>
Arm type*	Active comparator
Investigational medicinal product name*	Sonovue, Bracco
Investigational medicinal product code	
Other name	Sulfur hexafluoride
Pharmaceutical forms*	Powder and solvent for solution for intravenous infusion
Routes of administration*	ev
Dosage and administration details*	5 ml, ev infusion in 5 min

Number of subjects in period	Arm Title (overall population)	Arm Title (<i>repeat for each arms if applicable</i>)
Started*	0	
Completed*	54	
Subject non-completion reason (if applicable)		
AE, non fatal	none	
AE, fatal	none	
Consent withdrawn by subject	none	
Lack of efficacy	none	
Lost to follow up	none	
Physician decision	none	
Pregnancy	none	
Protocol Deviation	none	
Other	none	

Baseline characteristics

Reporting groups* Overall cohort

Reporting group title*	Transesophageal echocardiography prior to angiography
Number of subjects at the baseline*	54
Patient undergone to contrast enhanced Transesophageal echocardiography before angiography	

Subject analysis sets

Add a subject analysis set if you wish to report on groups different from the reporting group defined above (repeat if applicable)

Subject analysis set title* NOT APPLICABLE	
Subject analysis set type*	NOT APPLICABLE
Subject analysis set description*	NOT APPLICABLE
Number of subjects in subjects analysis set*	NOT APPLICABLE

Age characteristics*

Complete either the age categorical, age continuous or complete both these characteristics in order to collect values for the reporting groups and optionally the subject analysis sets.

	Characteristic title*	Units*	Age categories*
Age categorical	NOT APPLICABLE	NOT APPLICABLE	

	Characteristic title*	Units*	Central tendency*	Dispersion type*
Age continuous	Overall cohort	Years Months Weeks Days	Arithmetic Mean Median least square mean geometric mean log mean	full range (min-max) standard deviation inter quartile range

Gender characteristics*

	Characteristic title*	Units*	Gender categories*
Gender categorical	NOT APPLICABLE	NOT APPLICABLE	Female Male

Study specific characteristics

	Characteristic title*	Units*	Categories*	Number of subject for each categories
Study specific categorical				
Study specific categorical				
Study specific categorical				
Study specific categorical				
Study specific categorical				

End points

Add subject analysis set if you wish to report on groups different from reporting groups defined above

Subject analysis set title*	
Subject analysis set type*	Full Analysis Intention to treat Per protocol Safety analysis Sub-group analysis
Subject analysis set description*	
Number of subject in subject analysis set *	

End points definitions

End point title*	DIAGNOSTIC ACCURACY OF CONTRAST ENHANCED TRANSESOPHAGEAL ECHOCARDIOGRAPHY COMPARED TO ANGIOGRAPHY	
		Values
Countable or measurable?*	NO	-
If countable, Countable units*:	NO	
If measurable, Measurable units*:	NO	
Measure type*:	NO	
Precision/dyspersion type*	NO	

End point type*	Primary Secondary Other pre-specified Post Hoc
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End point timeframe*:

Use categories only if the data for the end point can be categorized

Category title

Specify the groups of subjects applicable to this end point

Reporting groups*	NOT APPLICABLE		
Period			
Arms			
subject analysis sets			

Adverse events

Adverse events information

NONE

Adverse event reporting additional description: *Enter information about the AE collection and provide details about the method of assessment and monitoring*

NONE

Assessment type*	Systematic
Frequency threshold for reporting non-serious adverse events*	NONE

Dictionary used

Dictionary name*	
Dictionary version*	

Adverse events reporting group definition

Use arms from baseline period as reporting groups
OR

Reporting group title*: *NOT APPLICABLE*

For this reporting group, provide the following totals:

Subject exposed*	
Subjects affected by non -SAE*	
Total number of deaths (all causes)*	
Total number of deaths resulting from adverse event*	

Serious adverse event details and values

System organ class*: NONE

Event term*:

Values for serious adverse event per reporting group *

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number	Occurrences causally related to treatment number	Fatalities number	Fatalities causally related to treatment number

Non - Serious adverse event details and values

System organ class*: NONE

Event term*: NONE

Values for non-serious adverse event per reporting group*

Threshold for non-serious adverse event reporting is:

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol*? **Yes** or **No**

Date	Amendment
11/08/2011	Follow up phone call

Notes:

Interruptions (globally)

Were there any global interruptions to the trial*? **Yes** or **No**

If Yes, Interruption date

Interruption description

Limitations and caveats

None reported

Online references

Agricola E, Slavich M, Bertoglio L, Civilini E, Melissano G, Marone E, Rinaldi E, Fiscaro A, Marini C, Tufaro V, Margonato A, Chiesa R. Contrast-Enhanced TEE During Thoracic Endovascular Aortic Repair Procedure. JACC Cardiovasc Imaging. 2015 Aug;8(8):980-2.

Agricola E, Slavich M, Rinaldi E, Bertoglio L, Civilini E, Melissano G, Marone E, Fiscaro A, Marini C, Tufaro V, Cappelletti A, Margonato A, Chiesa R. Usefulness of contrast-enhanced transoesophageal echocardiography to guide thoracic endovascular aortic repair procedure. Eur Heart J Cardiovasc Imaging. 2016 Jan;17(1):67-75.