Clinical trial results:
Ticagrelor and absorb bioresorbable vascular scaffold implantation for recovery of vascular function after successful chronic total occlusion recanalization

Summary

EudraCT number	2013-002675-17
Trial protocol	ES
Global end of trial date	15 May 2019

Results information

Result version number	v1 (current)
This version publication date	03 May 2021
First version publication date	03 May 2021
Summary attachment (see zip file)	final results (Informe final TIGER BVS_comentarios AZ_SB.pdf) trial design (TIGER-BVS Design paper - Final.docx) main findings (TIGER-BVS main paper 8.0.docx)

Trial information

Trial identification

Sponsor protocol code	TIGER-BVS

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	IDIBAPS
Sponsor organisation address	Carrer De Villaroel 170, Barcellona, Spain, 08036
Public contact	Servicio de Cardología, Hospital Clínic de Barcelona, 0034 9322754002042, sabrugal@clinic.ub.es
Scientific contact	Servicio de Cardología, Hospital Clínic de Barcelona, 0034 9322754002042, sabrugal@clinic.ub.es

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	21 November 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 May 2019
Global end of trial reached?	Yes
Global end of trial date	15 May 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the effects of ticagrelor vs. clopidogrel on the adenosine-induced physiological vascular function of the coronary segment distal to a coronary chronic total occlusion immediately after percutaneous recanalization.

Protection of trial subjects:

Subjects were strictly followed up

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 May 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Ethical reason, Regulatory reason, Scientific research
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

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)	78
From 65 to 84 years	22

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

screening was with few failed screening patients

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	clopidogrell

Arm description: -

Arm type	clopidogrel

No investigational medicinal product assigned in this arm

Arm title	ticagrelor

Arm description: -

Arm type	ticagrelor
Investigational medicinal product name	ticagrelor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Buccal tablet
Routes of administration	Oral use

Dosage and administration details:

loading dose of 180 mg, followed by 90 mg bid

Number of subjects in period 1	clopidogrell	ticagrelor
Started	50	50
Completed	50	50

Baseline characteristics

End points

End points reporting groups	
Reporting group title	clopidogrell
Reporting group description: -	
Reporting group title	ticagrelor
Reporting group description: -	

Primary: coronary blood flow	
End point title	coronary blood flow
End point description:	
End point type	Primary
End point timeframe: baseline	

End point values	clopidogrell	ticagrelor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: AUC				
arithmetic mean (standard deviation)	19604 (± 11244)	32122 (± 24039)		

Statistical analyses

Statistical analysis title	main endpoint analysis
Comparison groups	clopidogrell v ticagrelor
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	AUC
Point estimate	10000
Confidence interval	
level	90 %
sides	2-sided
lower limit	1000
upper limit	20000
Variability estimate	Standard deviation

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 3 years	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1.0

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

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: events were less than 1%

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