Clinical trial results:
Evaluation of a modified Anti-Platelet Therapy associated with low-dose rapamycin DES Firehawk in Acute Myocardial Infarction Patients treated with complete revascularization strategy (TARGET-FIRST)

Summary

EudraCT number	2020-005933-34
Trial protocol	AT NL ES IT PT
Global end of trial date	24 March 2025

Results information

Result version number	v1 (current)
This version publication date	27 March 2026
First version publication date	27 March 2026

Trial information

Trial identification

Sponsor protocol code	SFHI01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04753749
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	SORIN CRM SAS (Microport)
Sponsor organisation address	4 avenue reaumur, Clamart, France, 92140
Public contact	Clinical Affairs, Sorin CRM SAS (Microport CRM), +33 0146013409, yann.poezevara@crm.microport.com
Scientific contact	Clinical Affairs, Sorin CRM SAS (Microport CRM), 0607526971 0146013409, yann.poezevara@crm.microport.com

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	15 January 2026
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 March 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate a modified Anti-Platelet Therapy, associated with low-dose rapamycin DES Firehawk in Acute Myocardial Infarction Patients treated with complete revascularization strategy, in reaching non-inferior NACE (among clinically stable, low to moderate complexity acute MI patients).

Protection of trial subjects:

Pre-specified stopping rules

Background therapy:

Percutaneous Coronary Intervention in the setting of Acute Myocardial Infarction

Evidence for comparator:

Comparator is dual-antiplatelet (standard of care) for 12 months after PCI

Actual start date of recruitment	15 March 2021
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	Netherlands: 300
Country: Number of subjects enrolled	Italy: 148
Country: Number of subjects enrolled	France: 1525
Country: Number of subjects enrolled	Portugal: 1
Country: Number of subjects enrolled	Austria: 23
Country: Number of subjects enrolled	Spain: 249
Worldwide total number of subjects	2246
EEA total number of subjects	2246

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)	1384
From 65 to 84 years	831
85 years and over	31

Subject disposition

Recruitment

Recruitment details:

First Patient First Visit (Enroll. / Random.) 25/03/2021 (27/04/2021)
Last Patient First Visit (Enroll. / Random.) 06/03/2024 (15/04/2024)
Last Patient Last Visit 24/03/2025

Pre-assignment

Screening details:

Patients were eligible for randomization if successful PCI without complication, and compliant to DAPT treatment until randomizatio visit

Pre-assignment period milestones

Number of subjects started	2246
Number of subjects completed	2246

Period 1

Period 1 title	Pre-randomization
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	overall

Arm description:

1 month period after enrollment, until randomization

Arm type	Active comparator
Investigational medicinal product name	Efient
Investigational medicinal product code	PRD9985304
Other name	Prasugrel
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg daily

Investigational medicinal product name	Plavix
Investigational medicinal product code	PRD2912277
Other name	Clopidogrel
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

75 mg daily

Investigational medicinal product name	Brilique
Investigational medicinal product code	PRD3534050
Other name	Ticagrelor
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

90 mg twice daily

Investigational medicinal product name	ASPIRINE PROTECT
Investigational medicinal product code	PRD855688
Other name	Aspirin
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg daily

Number of subjects in period 1	overall
Started	2246
Completed	1942
Not completed	304
non-eligible	304

Period 2

Period 2 title	Randomization
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention

Arm description:

P2Y12 inhibitor Monotherapy

Arm type	Experimental
Investigational medicinal product name	Efient
Investigational medicinal product code	PRD9985304
Other name	Prasugrel
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg daily

Investigational medicinal product name	Plavix
Investigational medicinal product code	PRD2912277
Other name	Clopidogrel
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

75 mg daily

Investigational medicinal product name	Brilique
Investigational medicinal product code	PRD3534050
Other name	Ticagrelor
Pharmaceutical forms	Tablet

Routes of administration	Oral use

Dosage and administration details:
90 mg twice daily

Arm title	Control

Arm description:
DAPT

Arm type	Active comparator
Investigational medicinal product name	Efient
Investigational medicinal product code	PRD9985304
Other name	Prasugrel
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
10 mg daily

Investigational medicinal product name	Plavix
Investigational medicinal product code	PRD2912277
Other name	Clopidogrel
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
75 mg daily

Investigational medicinal product name	Brilique
Investigational medicinal product code	PRD3534050
Other name	Ticagrelor
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
90 mg twice daily

Investigational medicinal product name	ASPIRINE PROTECT
Investigational medicinal product code	PRD855688
Other name	Aspirin
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
100 mg daily

Number of subjects in period 2	Intervention	Control
Started	961	981
Completed	961	981

Baseline characteristics

Reporting groups	
Reporting group title	Pre-randomization

Reporting group description: -

Reporting group values	Pre-randomization	Total	
Number of subjects	2246	2246	
Age categorical Units: Subjects			
Adults (18-64 years)	1384	1384	
From 65-84 years	831	831	
85 years and over	31	31	
Gender categorical Units: Subjects			
Female	500	500	
Male	1746	1746	

End points

End points reporting groups

Reporting group title	overall
Reporting group description:	
1 month period after enrollment, until randomization	
Reporting group title	Intervention
Reporting group description:	
P2Y12 inhibitor Monotherapy	
Reporting group title	Control
Reporting group description:	
DAPT	

Primary: Net Adverse Clinical and Cerebrovascular Events (NACCE)

End point title	Net Adverse Clinical and Cerebrovascular Events (NACCE)[1]
End point description:	
NACCE is defined as the composite of all cause death, myocardial infarction, definite/probable study stent thrombosis, stroke, or BARC bleeding (type 3 or 5), at 11 months after randomization (334 days from randomization).	
End point type	Primary
End point timeframe:	
11 months post-randomization	

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: Study results uploaded in CTIS (transition trial)

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	961	981		
Units: Events	20	21		

Statistical analyses

No statistical analyses for this end point

Secondary: Bleeding events

End point title	Bleeding events
End point description:	
Bleeding events defined as BARC type 2, 3 or 5	
End point type	Secondary
End point timeframe:	
11 months post-randomization	

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	961	981		
Units: Events	25	54		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 12 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 3 %

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: Annual Safety Reports (ASR) were sent yearly to ANSM, AGEs, AIFA, AEMPS, CCMO and INFARMED.as well as all the ECs.
From 2023, Development Safety Update Report (DSUR) was sent to Italian authorities and it was published on CTIS in 2025.
No SUSAR in relation to the antiplatelet therapy was reported. No USADE related to the to stent was neither reported.
Final study report posted on CTIS (transitioned trial)

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/40888726