Clinical trial results: *Full title of Trial**

Summary

EudraCT number*	2012-000648-83
Trial protocol	IMPLAC
Global end of trial date*	31/12/2025

Trial information

Trial identification	
Sponsor protocol code*	10007541
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?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Results analysis stage	
Analysis stage*	Final
Date of interim/final analysis*	2016
Is this the analysis of the primary completion data?*	Yes
Global end of trial reached?*	Yes
Global end of trial date*	31/12/2015
Was the trial ended prematurely?	No

General information about the trial

Main objective of the trial*: *Enter a description for the mail objective(s) of the trial*

Actual start date of recruitment*	
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*:	No
Background therapy:	N/A
Evidence for comparator:	N/A

Population of trial subjects

Subjects enrolled per country

Country:	
Planned number of subjects	
Actual Number of subjects enrolled*	
Worldwide total number of subjects	
EEA total number of subjects	

Subjects enrolled per age group

In utero*	
Preterm newborn - gestational age < 37wks*	
Newborns (0-27 days)*	
Infants and toddlers (28 days-23months)*	
Children (2-11 years)*	
Adolescents (12-17 years)*	
Adults (18-64 years)*	
From 65 to 84 years*	
85 years and over*	

Subject disposition

Recruitment details: *Enter key information relevant to the recruitment process for the trial (eg gates of recruitment period and territories)*

Pre-assignment - *Screening details*: *Enter relevant information related to screening (eg screening criteria, significant events and approaches)*

Period 1	
Period title*	*Enter a title describing the stage of the trial. If the only one period is defined, the default title should be "Overall Trial"*
Is this the baseline period?	Yes or No
Allocation method*	Randomised - controlled Non-randomised - controlled Not applicable
Blinding used*	Double blind Single blind Not blinded

Arms	
Arm title*	*Enter a title to identify the arm - Add arm and IMP if applicable*
Arm description:	
Arm type*	Experimental Active comparator Placebo No intervention Other
Investigational medicinal product name*	
Investigational medicinal product code	
Other name	
Pharmaceutical forms*	
Routes of administration*	
Dosage and administration details*	

Number of subjects in period	Arm Title (overall population)	Arm Title *(repeat for each arms if applicable)*
Started*		
Completed*		
Subject non-completion reason (if applicable)		
AE, non fatal		
AE, fatal		
Consent withdrawn by subject		
Lack of efficacy		
Lost to follow up		
Physician decision		
Pregnancy		
Protocol Deviation		
Other		

Baseline characteristics

Reporting groups* Overall cohort	
Reporting group title*	
Number of subjects at the baseline*	

Reporting group description: *You can report per arm in the baseline period or for the overall baseline period*

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*	
Subject analysis set type*	Full Analysis Intention to treat Per protocol Safety analysis Sub-group analysis
Subject analysis set description*	*Enter a clear description which defines this set of subjects*
Number of subjects in subjects analysis set*	

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			

	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			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 form 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*		
		Values
Countable or measurable?*	*Select countable when the end point represents data that contains distinct values.*	-
If countable, Countable units*:		
If measurable, Measurable units*		
Measure type*:	Number Arithmetic Mean Median least square mean geometric mean log mean	
Precision/dyspersion type*		

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

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*			
Period			
Arms			
subject analysis sets			

Adverse events

Adverse events information

Timeframe for reporting adverse events*: *Enter the time point(s) or time period for AE assessment*

First patient first visit:
Last recruitment date:
Study closure:

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

Assessment type*	Systematic or Non Systematic
Frequency threshold for reporting non-serious adverse events*	*Enter the frequency of non SAE that are reported in the results database for all arms or reporting groups*

Dictionary used

Dictionary name*	MedDRA or CTCAE
Dictionary version*	

Adverse events reporting group definition

Use arms from baseline period as reporting groups
OR

Reporting group title*: *Overall cohort*

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*:

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*:

Event term*:

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

Notes:

Interruptions (globally)

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

If Yes, Interruption date

Interruption descrption

Limitations and caveats

None reported

Online references

Enter PubMed identifier (PMID)

Int J Cardiol Heart Vasc. 2018 Dec; 21: 32–35. Published online 2018 Sep 25. doi: 10.1016/j.ijcha.2018.09.005
PMCID: PMC6161414

Int J Cardiol Heart Vasc. 2020 Oct; 30: 100619. Published online 2020 Aug 20. doi: 10.1016/j.ijcha.2020.100619
PMCID: PMC7452655

PLoS One. 2018; 13(2): e0192600. Published online 2018 Feb 12. doi: 10.1371/journal.pone.0192600
PMCID: PMC5809053

Mediators Inflamm. 2015; 2015: 718329. Published online 2015 Apr 16. doi: 10.1155/2015/718329
PMCID: PMC4415469

Clin Exp Immunol. 2015 Feb; 179(2): 173–187. Published online 2015 Jan 2. doi: 10.1111/cei.12477
PMCID: PMC4298395

Brain Behav. 2019 Oct; 9(10): e01429. Published online 2019 Sep 30. doi: 10.1002/brb3.1429
PMCID: PMC6790304