Clinical trial results:
68Ga-NODAGA-RGD cardiac PET in patients with acute myocardial infarction or chronic total coronary occlusion

Summary

EudraCT number	2014-004392-23
Trial protocol	FI
Global end of trial date	11 February 2023

Results information

Result version number	v1 (current)
This version publication date	08 January 2025
First version publication date	08 January 2025

Trial information

Trial identification

Sponsor protocol code	T189/2016

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04871217
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Turku University Hospital
Sponsor organisation address	Kiinamyllynkatu 4-8, Turku, Finland, 20520
Public contact	Turku University Hospital, Heart Center, Turku University Hospital, +358 23130083, antti.saraste@utu.fi
Scientific contact	Turku University Hospital, Heart Center, Turku University Hospital, +358 23130083, antti.saraste@utu.fi

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	16 November 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 February 2023
Global end of trial reached?	Yes
Global end of trial date	11 February 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluate PET imaging with 68Ga-NODAGA-RGD in patients with acute or chronic coronary artery occlusion

Protection of trial subjects:

None

Background therapy:

Guideline directed medical therapy of acute myocardial infarction/chronic coronary artery disease

Evidence for comparator:

None

Actual start date of recruitment	31 January 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 31
Worldwide total number of subjects	31
EEA total number of subjects	31

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)	12
From 65 to 84 years	19

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Prospective recruitment of patients with first ST-elevation acute myocardial infarction from December 2018 to January 2021 in Turku University Hospital, Finland.

Pre-assignment

Screening details:

Patients with first ST-elevation acute myocardial infarction were screened.

Period 1

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

Blinding implementation details:

Unblinded trial

Arms

Arm title	Single arm

Arm description:

Cardiac PET scan after injection of [68Ga]Ga-NODAGA-RGD

Arm type	Experimental
Investigational medicinal product name	68Ga-NODAGA-RGD
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Injection

Dosage and administration details:

An average of 179 +/- 15 MBq of 68Ga-NODAGA-RGD was injected as an intravenous bolus.

Number of subjects in period 1	Single arm
Started	31
Completed	31

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	31	31	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	64		
standard deviation	± 9	-	
Gender categorical Units: Subjects			
Female	3	3	
Male	28	28	

End points

End points reporting groups

Reporting group title	Single arm

Reporting group description:

Cardiac PET scan after injection of [68Ga]Ga-NODAGA-RGD

Primary: 68Ga-NODAGA-RGD uptake in myocardial area at risk

End point title	68Ga-NODAGA-RGD uptake in myocardial area at risk[1]

End point description:

Uptake of 68Ga-NODAGA-RGD in the myocardial area at risk was significantly higher than in the remote myocardium of the same patients ($p<0.001$).

End point type	Primary

End point timeframe:

3-14 days after ST-elevation myocardial infarction

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 end point was not compared between groups in this single arm study (explanation in end point definition section)

End point values	Single arm			
Subject group type	Reporting group			
Number of subjects analysed	31[2]			
Units: SUV				
arithmetic mean (standard deviation)	0.7 (± 0.2)			

Notes:

[2] - Single arm trial

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

2 years from baseline (from Dec 2018 to Feb 2023)

Adverse event reporting additional description:

Clinical evaluation (visits at baseline and at 6 months) and electronic medical records (2-year follow-up). Adverse events included death, myocardial infarction and heart failure hospitalization.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Single arm

Reporting group description: -

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: Only one (serious) adverse event in this small diagnostic trial

Serious adverse events	Single arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 31 (3.23%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Myocardial infarction	Additional description: Non–ST-elevation acute myocardial infarction caused by a coronary lesion other than the index lesion 6 months after baseline. Unrelated to the investigational product.		
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Single arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 31 (0.00%)		

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/37973184