Clinical trial results:
Phase II: 68Ga-NODAGA-E[c(RGDyK)]2 Angiogenese PET for imaging angiogenesis in ST-Elevation Myocardial Infarction(STEMI)

Summary

EudraCT number	2017-002709-36
Trial protocol	DK
Global end of trial date	09 July 2020

Results information

Result version number	v1 (current)
This version publication date	21 July 2021
First version publication date	21 July 2021

Trial information

Trial identification

Sponsor protocol code	AK2017-3

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03445884
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark, 2100
Public contact	Simon Bentsen, Rigshospitalet, Department og Clinical Physiology, Nuclear Medicine and PET, 0045 35451793, simon.bentsen.01@regionh.dk
Scientific contact	Simon Bentsen, Rigshospitalet, Department og Clinical Physiology, Nuclear Medicine and PET, 0045 35451793, simon.bentsen.01@regionh.dk

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	05 July 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 July 2020
Global end of trial reached?	Yes
Global end of trial date	09 July 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to test a new radio tracer called 68Ga-NODAGA-E-[RGDyK]2 for PET imaging of angiogenesis. The tracer has the potential of identifying heart tissue with a high level of angiogenesis. Angiogenesis is a very important factor in reparing heart tissue after an heartattack. therefor, the tracer can potentially be used to asses how the tissue respons to the chosen therapy.

Protection of trial subjects:

The study investigated a new radiotracer for detecting angiogenesis. There were no discomfort or pain associated with the study of the new tracer.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 October 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 42
Worldwide total number of subjects	42
EEA total number of subjects	42

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)	23
From 65 to 84 years	19
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All patients admitted to the department of cardiology that were diagnosed with ST-elevation myocardial infarction, were screened after admission.

Pre-assignment

Screening details:

All patients with STEMI were screened before enrollment in the study by a physician. The inclusion criteria were : STEMI-group: > 50 years of age with verified STEMI, control group: >18 years with no recording of disease.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	STEMI

Arm description:

The STEMI group was PET/CT scanned with RGD-PET acute, after one week and after four weeks

Arm type	Experimental
Investigational medicinal product name	68Ga-NODAGA-E[c(RGDyK)]2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

At each scan the patient were injected with ~200 MBq of 68Ga-NODAGA-E[c(RGDyK)]2

Arm title	Control group

Arm description: -

Arm type	healthy control group
Investigational medicinal product name	68Ga-NODAGA-E[c(RGDyK)]2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

At each scan the patient were injected with ~200 MBq of 68Ga-NODAGA-E[c(RGDyK)]2

Number of subjects in period 1	STEMI	Control group
Started	37	5
Completed	32	5
Not completed	5	0
Consent withdrawn by subject	1	-
Lost to follow-up	4	-

Baseline characteristics

Reporting groups	
Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	42	42	
Age categorical Units: Subjects			
Adults (18-64 years)	23	23	
From 65-84 years	19	19	
Gender categorical Units: Subjects			
Female	10	10	
Male	32	32	

End points

End points reporting groups

Reporting group title	STEMI
Reporting group description:	
The STEMI group was PET/CT scanned with RGD-PET acute, after one week and after four weeks	
Reporting group title	Control group
Reporting group description: -	

Primary: RGD-PET uptake in the myocardium acute

End point title	RGD-PET uptake in the myocardium acute[1]
End point description:	
End point type	Primary
End point timeframe:	
The SUV uptake in the infarcted area after the acute scan	

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: It is not possible to report the paired t-test result between mean SUV uptake in the infarcted area and healthy myocardium. Therefore, the results of these data will be available in the pending manuscript.

End point values	STEMI	Control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	5		
Units: gram(s)/millilitre				
median (standard deviation)	1.43 (± 0.37)	1.15 (± 0.12)		

Statistical analyses

No statistical analyses for this end point

Primary: RGD-PET uptake in the myocardium after one week

End point title	RGD-PET uptake in the myocardium after one week[2][3]
End point description:	
End point type	Primary
End point timeframe:	
The SUV uptake in the infarcted area after one week.	

Notes:

[2] - 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: It is not possible to report the paired t-test result between mean SUV uptake in the infarcted area and healthy myocardium. Therefore, the results of these data will be available in the pending manuscript.
[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the

baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: It is not possible to report the paired t-test result between mean SUV uptake in the infarcted area and healthy myocardium. Therefore, the results of these data will be available in the pending manuscript.

End point values	STEMI			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: gram(s)/millilitre				
median (standard deviation)	2.1 (± 0.46)			

Statistical analyses

No statistical analyses for this end point

Primary: RGD-PET uptake in the myocardium after four weeks

End point title	RGD-PET uptake in the myocardium after four weeks[4][5]

End point description:

End point type	Primary

End point timeframe:

The SUV uptake in the infarcted area after four weeks

Notes:

[4] - 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: It is not possible to report the paired t-test result between mean SUV uptake in the infarcted area and healthy myocardium. Therefore, the results of these data will be available in the pending manuscript.
[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: It is not possible to report the paired t-test result between mean SUV uptake in the infarcted area and healthy myocardium. Therefore, the results of these data will be available in the pending manuscript.

End point values	STEMI			
Subject group type	Reporting group			
Number of subjects analysed	31			
Units: gram(s)/millilitre				
median (standard deviation)	2.04 (± 0.56)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All participants were monitored 48 hours after injection of the radiotracer.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10

Reporting groups

Reporting group title	STEMI

Reporting group description:

The STEMI group was PET/CT scanned with RGD-PET acute, after one week and after four weeks

Reporting group title	Control group

Reporting group description:

In the healthy controlgroup the person were PET/CT scanned one time with RGD-PET.

Serious adverse events	STEMI	Control group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 37 (0.00%)	0 / 5 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	STEMI	Control group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 37 (0.00%)	0 / 5 (0.00%)	

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: There were no adverse event in this study.

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