



Clinical trial results: In vivo molecular imaging of angiogenesis after VEGF-D gene therapy Summary

EudraCT number	2018-001494-24
Trial protocol	DK
Global end of trial date	01 June 2023

Results information

Result version number	v1 (current)
This version publication date	16 December 2024
First version publication date	16 December 2024

Trial information

Trial identification

Sponsor protocol code	AK2015-10
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark, 2100
Public contact	Rasmus Ripa, Rigshospitalet, Department of Clinical Physiology, Nuclear Medicine and PET, 45 35454011, rasmus.ripa@regionh.dk
Scientific contact	Rasmus Ripa, Rigshospitalet, Department of Clinical Physiology, Nuclear Medicine and PET, 45 35454011, rasmus.ripa@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	26 September 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 June 2023
Global end of trial reached?	Yes
Global end of trial date	01 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To use 68Ga-NODAGA-E[c(RGDyK)]₂ PET/CT scans as a tool to image myocardial angiogenesis

Protection of trial subjects:

The study investigated a new i.v. 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	05 March 2020
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: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	8
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study population was recruited at a single center in Copenhagen, Denmark from March 2020 until October 2022.

Pre-assignment

Screening details:

All participants in the ReGenHeart study (2017-000789-31) recruited in Denmark were screened for inclusion.

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Subject, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	VEGF treatment

Arm description: -

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 use

Dosage and administration details:

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

Arm title	Control
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Arm description: -

Arm type	Placebo
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 use

Dosage and administration details:

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

Number of subjects in period 1	VEGF treatment	Control
Started	11	5
Completed	7	5
Not completed	4	0
Consent withdrawn by subject	2	-

Adverse event, non-fatal	1	-
withdrew from ReGenHeart-treatment	1	-

Baseline characteristics

Reporting groups

Reporting group title	VEGF treatment
Reporting group description: -	
Reporting group title	Control
Reporting group description: -	

Reporting group values	VEGF treatment	Control	Total
Number of subjects	11	5	16
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	66	61	
full range (min-max)	59 to 78	44 to 75	-
Gender categorical Units: Subjects			
Female	1	1	2
Male	10	4	14

End points

End points reporting groups

Reporting group title	VEGF treatment
Reporting group description: -	
Reporting group title	Control
Reporting group description: -	

Primary: Cardiac 68Ga-RGD uptake

End point title	Cardiac 68Ga-RGD uptake
End point description:	
End point type	Primary
End point timeframe:	
From baseline to 6 months after VEGF treatment	

End point values	VEGF treatment	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	5		
Units: RAW				
arithmetic mean (standard deviation)	208 ($\pm$ 391)	26 ($\pm$ 430)		

Statistical analyses

Statistical analysis title	Primary endpoint
Comparison groups	VEGF treatment v Control
Number of subjects included in analysis	12
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4
Method	t-test, 2-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All participants were monitored 24 hours after injection of the radiotracer for adverse events. In addition, participants were asked about potential adverse events occurring in the period between the 3 scans (3-4 months)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	10

Reporting groups

Reporting group title	All included
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Reporting group description:

All subjects treated with at least one dose of IMP

Serious adverse events	All included		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All included		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 15 (33.33%)		
Cardiac disorders			
Vertigo	Additional description: Self limiting		
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Nervous system disorders			
Headache	Additional description: Self limiting headache during scan		
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
General disorders and administration site conditions			
Influenza	Additional description: Influenza-like symptoms. Self limiting		

subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Renal and urinary disorders			
Cystitis	Additional description: asymptomatic		
subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Endocrine disorders			
Diabetes mellitus management	Additional description: Mild dysregulation of diabetes		
subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

It was not possible to include the planned number of subjects.
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Notes: