



Clinical trial results:

[68Ga]Ga-DOTA-(RGD)2 PET/CT imaging of activated endothelium in lung parenchyma of COVID-19 patients.

Summary

EudraCT number	2020-001325-31
Trial protocol	NL
Global end of trial date	08 June 2021

Results information

Result version number	v1 (current)
This version publication date	24 June 2022
First version publication date	24 June 2022

Trial information

Trial identification

Sponsor protocol code	NL73551.091.20
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04596943
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Radboud University Medical Center
Sponsor organisation address	Geert Grooteplein zuid 8, Nijmegen, Netherlands, 6525 GA
Public contact	Nuclear Medicine Research Office, Radboud University Medical Center, +31 24367243, Michel.deGroot@radboudumc.nl
Scientific contact	Nuclear Medicine Research Office, Radboud University Medical Center, +31 24367243, Michel.deGroot@radboudumc.nl

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	27 January 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 January 2021
Global end of trial reached?	Yes
Global end of trial date	08 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to demonstrate and quantitate aberrant activation of the endothelium in the lung vasculature using [68Ga]Ga-DOTA-(RGD)2 PET/CT.

Protection of trial subjects:

Best standard of care.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 October 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	Netherlands: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	4
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment from 16-OCT-2020 up to 27-Jan-2021. 10 patients screened, 10 patients enrolled.

Pre-assignment

Screening details:

No pre-assignment period applicable.

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:

Blinding not applicable.

Arms

Arm title	Interventional arm
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Arm description:

Single arm, injection of radiotracer followed by PET-CT imaging.

Arm type	Experimental
Investigational medicinal product name	[89Ga]Ga-DOTA-E-[c(RGDfK)]2
Investigational medicinal product code	SUB130779
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

Mean dose 196 +/- 20 MBq, single injection

Number of subjects in period 1	Interventional arm
Started	10
Completed	10

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	10	10	
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			
Median (IQR) age range = 68.5 (52.0-74.5] years			
Units: years			
median	68.5		
inter-quartile range (Q1-Q3)	52.0 to 74.5	-	
Gender categorical			
Gender categorical			
Units: Subjects			
Female	3	3	
Male	7	7	

End points

End points reporting groups

Reporting group title	Interventional arm
Reporting group description:	
Single arm, injection of radiotracer followed by PET-CT imaging.	

Primary: Primary End Point

End point title	Primary End Point ^[1]
End point description:	
Radiotracer uptake in lungs	
End point type	Primary
End point timeframe:	
Overall study	

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: Observational trial with descriptive end points only.

End point values	Interventional arm			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Standardized Uptake Value (SUV)				
number (not applicable)	10			

Attachments (see zip file)	SUV_lungs/SUV_lungs.jpg
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Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Overall study

Adverse event reporting additional description:

CTCAE v. 4.03

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4.03
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Frequency threshold for reporting non-serious adverse events: 0 %

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: No non-serious adverse events occurred outside of events related to the disease.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 October 2020	Prior to first subject in diagnostic CE-CT was removed from inclusion criteria.

Notes:

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.

Not applicable.

Notes: