Clinical trial results:
Phase II trial: RGD PET/MRI in sporadic Vestibular Schwannoma

Summary

EudraCT number	2017-002604-27
Trial protocol	DK
Global end of trial date	16 March 2021

Results information

Result version number	v1 (current)
This version publication date	12 March 2023
First version publication date	12 March 2023

Trial information

Trial identification

Sponsor protocol code	PCT2017-1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03393689
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Copenhagen University Hospital Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, Copenhagen OE, Denmark, 2100
Public contact	Hjalte Christian Reeberg Sass, Rigshospitalet, Department of Otorhinolaryngology, Head and Neck Surgery & Audiology , 0045 31310730, hjaltesass@gmail.com
Scientific contact	Hjalte Christian Reeberg Sass, Rigshospitalet, Department of Otorhinolaryngology, Head and Neck Surgery & Audiology , 31310730 31310730, hjaltesass@gmail.com

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	08 November 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 March 2021
Global end of trial reached?	Yes
Global end of trial date	16 March 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objektive of this study is to test whether the new radio tracer 68Ga-NODAGA-E[c(RGDyK)]2 for PET imaging of angiogenises. The tracer combined with PET-MR has the potential to provide a novel non-invasive prognostic method for the growth rate of vestibularis schwannomas, as the growth rate of vestibularis schwannomas has been correlated with pro-angiogenetic markers.
This is a phase II trial in patients with a benign intracranial tumor. Uptake of the tracer will be correlated to the growth rate by PET-MR and MR scans.

Protection of trial subjects:

The information regarding included patietns are protected by the health care legislation. Source data i saved in a electronic database, and is pseudoanonymised.
Kildedata (og CRF) gemmes i selvstændig mappe og overføres til en elektronisk database. Patientdata is protected throgh Pseudonymization and is kept in 10 years.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 43
Worldwide total number of subjects	43
EEA total number of subjects	43

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)	24
From 65 to 84 years	19
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The patients are included via the department of Otolaryngologi, Head & Neck surgery, Rigshospitalet and from the department of Audiology at Hillerød Hospital. 40 patients are included over a period expected to last 12 months.

Pre-assignment

Screening details:

Inclusion criteria. Patients > 18 years of age with an MRI diagnosed sporadic vestibular shcwannoma. Patients > 18 år with a maximal Wachful Waiting Regime of 12 months or 1 follow-up MRI.
Exclusion criteria. Pregnancy, lactation, Non-MRI compatible implants, Claustrofobia, Hormone-treatment, Steroidtreatment, weight > 140, allergy to PET-tracer

Period 1

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

Blinding implementation details:

This was a non-blinded non-randomized phase two clinical trial

Arms

Arm title	Intervention

Arm description:

PET-MRI scan with novel PET-Tracer. Follow-up MRI-scans with gadolinium contrast after 6 months and 12 months.

Arm type	Experimental
Investigational medicinal product name	[68Ga]NOTA -Asp-Cha-Phe-D-Ser-D-Arg-Tyr-Leu-Trp-Ser-OH
Investigational medicinal product code	
Other name	68Ga-NODAGA-E[c(RGDyK)]2, RGD
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Injection of 200 mBq through a peripheral venous catheter.

Number of subjects in period 1	Intervention
Started	43
Follow up Scan	37
Completed	37
Not completed	6
Not able to perform scan due to claustrophobia	6

Baseline characteristics

Reporting groups	
Reporting group title	Intevention (overall period)
Reporting group description:	
Patients newly diagnosed with a vestibular schwannoma, where knowledge regarding the potential growth of the schwannoma is not known.	

Reporting group values	Intevention (overall period)	Total	
Number of subjects	43	43	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	24	24	
From 65-84 years	19	19	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	60		
full range (min-max)	30 to 81	-	
Gender categorical Units: Subjects			
Female	21	21	
Male	22	22	

End points

End points reporting groups

Reporting group title	Intervention

Reporting group description:

PET-MRI scan with novel PET-Tracer. Follow-up MRI-scans with gadolinium contrast after 6 months and 12 months.

Primary: SUV uptake correlated to growth rate

End point title	SUV uptake correlated to growth rate[1]

End point description:

End point type	Primary

End point timeframe:

Patients are followed for a minimum of 12 months after primary PET-MRI scan, with follow-up scans.

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: Data analysis has been performed and will be published in a peer-reviewed article soon. Full data is available as uploaded as an XML document.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: Uptake correlated to growth				
number (not applicable)				
SUV uptake correlated to growth	37			

Attachments (see zip file)	Resultater.xlsx

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

The timeframe for the adverse events reporting was within the first 24-hours of administering the novel PET-tracer, RGD.

Assessment type	Systematic

Dictionary used

Dictionary name	none
Dictionary version	0

Reporting groups

Reporting group title	Internvention

Reporting group description: -

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

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

Non-serious adverse events	Internvention		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 37 (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: We did not see any adverse events during the 24-hour reporting timeframe.

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.

Limitations include the values of the SUV uptake in the smaller tumors as well as the genereal limitation in ROI-drawing, despite being done by two skilled radiologist.

Notes: