Clinical trial results:
68Ga-PSMA-PET/CT imaging for locally advanced, recurrent and metastatic adenoid cystic carcinoma or salivary duct carcinoma

Summary

EudraCT number	2017-002093-40
Trial protocol	NL
Global end of trial date	14 May 2018

Results information

Result version number	v1 (current)
This version publication date	24 June 2022
First version publication date	24 June 2022
Summary attachment (see zip file)	full_paper (20200110_PSMAPET_ACC_SDC.pdf)

Trial information

Trial identification

Sponsor protocol code	104902

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03319641
WHO universal trial number (UTN)	-
Other trial identifiers	NL61699.091.17: CCMO dossier code

Notes:

Sponsors

Sponsor organisation name	Radboud university medical center
Sponsor organisation address	Geert Grooteplein Zuid 10, Nijmegen, Netherlands,
Public contact	Carla M.L. van Herpen, Radboudumc, +31 0243667251, carla.vanherpen@radboudumc.nl
Scientific contact	Carla M.L. van Herpen, Radboudumc, +31 0243667251, carla.vanherpen@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	14 May 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 May 2018
Global end of trial reached?	Yes
Global end of trial date	14 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the uptake of 68Ga-PSMA in locally advanced, recurrent and metastatic ACC/SDC by performing 68Ga-PSMA-PET/CT scans

Protection of trial subjects:

68Ga-PSMA-PET/CT imaging is a imaging modality which is well known and often used in patients with recurrent prostate cancer. In these patients, no serious side effect have been reported. There is no reason to expect otherwise in our study population of patients with incurable ACC or SDC. In case unexpected side-effect do occur, the facilities to deliver emergency medical support are available at the study center. Therefore, we conclude that the risk of injury is small and if an injury occurs, it will be minor, which means the risk classification is negligible according to the NFU-risk classification.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 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	Netherlands: 25
Worldwide total number of subjects	25
EEA total number of subjects	25

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)	15

From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Source population:
- Patients with locally advanced, recurrent or metastatic ACC/SDC who are treated at the Department of Medical Oncology of the Radboudumc.
- Patients with locally advanced, recurrent or metastatic ACC/SDC who heard or read about this study and contact the investigators to ask whether they can take part in the study.

Pre-assignment

Screening details:

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- locally advanced, recurrent or metastatic ACC/SDC
- Age ≥ 18 years old
- Ability to provide written informed consent

Period 1

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

Arms

Arm title	single arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	68Ga-PSMA-HBED-CC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

2MBq/kg body weight

Number of subjects in period 1	single arm
Started	25
Completed	25

Baseline characteristics

Reporting groups	
Reporting group title	trial

Reporting group description: -

Reporting group values	trial	Total	
Number of subjects	25	25	
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)	15	15	
From 65-84 years	10	10	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	4	4	
Male	21	21	

End points

End points reporting groups	
Reporting group title	single arm
Reporting group description: -	
Subject analysis set title	final analysis
Subject analysis set type	Full analysis
Subject analysis set description: final analysis	

Primary: tumor/liver-ratio >1	
End point title	tumor/liver-ratio >1
End point description: the percentage of patients with a tumor/liver-ratio >1	
End point type	Primary
End point timeframe: n.a.	

End point values	single arm	final analysis		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	25	25		
Units: ratio				
number (not applicable)	25	25		

Statistical analyses

Statistical analysis title	tumor/liver ratio
Comparison groups	single arm v final analysis
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 5 [2]
Method	n.a., see comment
Parameter estimate	n.a.

Notes:

[1] - a ratio was described without statistical testing because of the low number of patients

[2] - the primairy outcome was not statistically tested. this was a hypothesis generating study without formal testing

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: whole trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.03

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

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: 68Ga-PSMA-PET/CT imaging is a imaging modality which is well known and often used in patients with recurrent prostate cancer. In these patients, no serious
side effect have been reported. There is no reason to expect otherwise in our study population of patients with incurable ACC or SDC. In case unexpected side-effect do
occur, the facilities to deliver emergency medical support are available at the study center.
In this study, no adverse events were recorded.

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