Clinical trial results:
Use of 18F-PSMA-11 PET for detection of lesions in iodine refractory thyroid cancers

Summary

EudraCT number	2021-000456-19
Trial protocol	BE
Global end of trial date	18 July 2023

Results information

Result version number	v1 (current)
This version publication date	26 September 2024
First version publication date	26 September 2024
Summary attachment (see zip file)	Final Study Report (2021-000456-19_18F-PSMA-11-PET_Final_Study_Report.pdf)

Trial information

Trial identification

Sponsor protocol code	BC-09501

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Hospital ghent
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	HIRUZ CTU, University Hospital Ghent, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	HIRUZ CTU, University Hospital Ghent, +32 93320500, hiruz.ctu@uzgent.be

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	02 September 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Demonstrate uptake of 18F-PSMA-11 in lesions in a radio-active iodine refractive thyroid carcinoma (RAI-RTC), either local recurrent disease, lymph nodes or distant metastasis.

Protection of trial subjects:

See attachment

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2021
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	Belgium: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See Final Study Report in attachment

Pre-assignment

Screening details:

See Final Study Report in attachment

Period 1

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

Blinding implementation details:

See Final Study Report in attachment

Arms

Arm title	Overal Trial

Arm description:

See Final Study Report in attachment

Arm type	Active comparator
Investigational medicinal product name	18F PSMA-11
Investigational medicinal product code	1940 IMP
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

See Final Study Report in attachment

Number of subjects in period 1	Overal Trial
Started	8
Completed	8

Baseline characteristics

End points

End points reporting groups

Reporting group title	Overal Trial

Reporting group description:

See Final Study Report in attachment

Primary: Demonstrate uptake of 18F-PSMA-11 in lesions

End point title	Demonstrate uptake of 18F-PSMA-11 in lesions[1]

End point description:

End point type	Primary

End point timeframe:

During the 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: See Final Study Report in attachment

End point values	Overal Trial			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: See attachment				
number (not applicable)	8			

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary endpoints

End point title	Secondary endpoints

End point description:

End point type	Secondary

End point timeframe:

See Final Study Report in attachment

End point values	Overal Trial			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: See Attachment				
number (not applicable)	8			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

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: See Final Study Report in attachment

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