Clinical trial results:
A Prospective Study on 18F-DCFPyL PET/CT Imaging in Biochemical Recurrence of Prostate Cancer

Summary

EudraCT number	2020-000121-37
Trial protocol	FR BE NL
Global end of trial date	12 October 2021

Results information

Result version number	v1 (current)
This version publication date	06 October 2023
First version publication date	06 October 2023

Trial information

Trial identification

Sponsor protocol code	2020-PSMA

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04734184
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CURIUM PET France
Sponsor organisation address	3 rue Marie Curie, Saint Beauzire, France, 63360
Public contact	Aurélie ETRINGER, ICTA PM, 33 380534039, aurelie.etringer@icta.fr
Scientific contact	Aurélie ETRINGER, ICTA PM, 33 380534039, aurelie.etringer@icta.fr

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 May 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 January 2021
Global end of trial reached?	Yes
Global end of trial date	12 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Per-patient detection rate of 18F-DCFPyL PET/CT versus that of 18F-FCH PET/CT

Protection of trial subjects:

No specific measures put in place

Background therapy:

None

Evidence for comparator:

18F-fluorocholine is a PET tracer marketed in Europe

Actual start date of recruitment	05 May 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: 9
Country: Number of subjects enrolled	Spain: 70
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	France: 135
Worldwide total number of subjects	217
EEA total number of subjects	217

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)	40
From 65 to 84 years	175

85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Patients with prostate cancer presenting a biochemical recurrence after curative initial therapy

Pre-assignment

Screening details:

•Male
•Age≥18 years
•Histopathological proven prostate adenocarcinoma per original diagnosis
•First suspected recurrence of PCa based on rising prostate-specific antigen (PSA) after initial curative therapy with radical prostatectomy ,of PSA ≥ 0.2 ng/mL confirmed by a subsequent PSA level of ≥0.2 ng/mL, or in case of radiation therapy (external

Period 1

Period 1 title	Baseline (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	18F-DCFPyl followed by 18F-Fluorocholine

Arm description:

Each patient receives 18F-DCFPyL followed by 18F-Fluorocholine within 12 days

Arm type	cross-over
Investigational medicinal product name	18FDCFPyL
Investigational medicinal product code	
Other name	PYLCLARI
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

330 MBq

Investigational medicinal product name	18F-fluorocholine
Investigational medicinal product code	
Other name	PROSTATEP
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intravenous use

Dosage and administration details:

2 - 4 MBq/kg

Arm title	18F-fluorocholine followed by 18F-DCFPyL

Arm description:

each patient receives 18F-fluorocholine followed by 18F-DCFPyL within 12 days

Arm type	cross-over
Investigational medicinal product name	18F-fluorocholine
Investigational medicinal product code	
Other name	PROSTATEP
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

2-4 MBq/kg

Investigational medicinal product name	18F-DCFPyL
Investigational medicinal product code	
Other name	PYLCLARI
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

330 MBq

Number of subjects in period 1	18F-DCFPyl followed by 18F-Fluorocholine	18F-fluorocholine followed by 18F-DCFPyL
Started	108	109
Completed	108	107
Not completed	0	2
Physician decision	-	2

Baseline characteristics

Reporting groups	
Reporting group title	18F-DCFPyl followed by 18F-Fluorocholine
Reporting group description:	
Each patient receives 18F-DCFPyL followed by 18F-Fluorocholine within 12 days	
Reporting group title	18F-fluorocholine followed by 18F-DCFPyL
Reporting group description:	
each patient receives 18F-fluorocholine followed by 18F-DCFPyL within 12 days	

Reporting group values	18F-DCFPyl followed by 18F-Fluorocholine	18F-fluorocholine followed by 18F-DCFPyL	Total
Number of subjects	108	109	217
Age categorical			
Units: Subjects			
Adults (18-64 years)	20	20	40
From 65-84 years	87	88	175
85 years and over	1	1	2
Age continuous			
70.0			
Units: years			
arithmetic mean	70.0	70.0	
standard deviation	± 7.1	± 7.1	-
Gender categorical			
Male only			
Units: Subjects			
Female	0	0	0
Male	108	109	217
initial curative treatment			
Patients have initially been treated by surgery or radiotherapy			
Units: Subjects			
surgery	81	77	158
radiotherapy	27	32	59

Subject analysis sets	
Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
Patients who have received at least one injection	
Subject analysis set title	18F-DCFPyL
Subject analysis set type	Full analysis
Subject analysis set description:	
Patients who received 18F-DCFPyL	
Subject analysis set title	18F-Fluorocholine
Subject analysis set type	Full analysis
Subject analysis set description:	
Patients who received 18F-fluorocholine	

Reporting group values	Full analysis set	18F-DCFPyL	18F-Fluorocholine
Number of subjects	205	205	205
Age categorical Units: Subjects			
Adults (18-64 years)	40		
From 65-84 years	163		
85 years and over	2		
Age continuous			
70.0			
Units: years			
arithmetic mean	70.0	70.0	70.0
standard deviation	± 7.1	± 7.1	± 7.1
Gender categorical			
Male only			
Units: Subjects			
Female	0		
Male	205		
initial curative treatment			
Patients have initially been treated by surgery or radiotherapy			
Units: Subjects			
surgery	150		
radiotherapy	55		

End points

End points reporting groups

Reporting group title	18F-DCFPyl followed by 18F-Fluorocholine
Reporting group description: Each patient receives 18F-DCFPyL followed by 18F-Fluorocholine within 12 days	
Reporting group title	18F-fluorocholine followed by 18F-DCFPyL
Reporting group description: each patient receives 18F-fluorocholine followed by 18F-DCFPyL within 12 days	
Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description: Patients who have received at least one injection	
Subject analysis set title	18F-DCFPyL
Subject analysis set type	Full analysis
Subject analysis set description: Patients who received 18F-DCFPyL	
Subject analysis set title	18F-Fluorocholine
Subject analysis set type	Full analysis
Subject analysis set description: Patients who received 18F-fluorocholine	

Primary: Per-patient detection rate

End point title	Per-patient detection rate
End point description: Images were read by 3 independent " blinded " readers. Per-patient detection rate was computed for each reader independently	
End point type	Primary
End point timeframe: Overall study	

End point values	18F-DCFPyL	18F-Fluorocholine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	205	205		
Units: percent	58	40		

Statistical analyses

Statistical analysis title	prescott's test
Statistical analysis description: The Prescott’s test was used to assess the difference between the two methods in term of detection. On the FAS, only “observed cases” were taken into account (i.e., no imputation was performed, and was considered as “assessed” in all patients with at least an evaluation by one of the independent readers) . The per-patient detection rate was computed for each reader independently .	
Comparison groups	18F-DCFPyL v 18F-Fluorocholine

Number of subjects included in analysis	410
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.001
Method	Prescott's test
Parameter estimate	Mean difference (net)
Point estimate	0.8
Confidence interval	
level	95 %
sides	1-sided
lower limit	0.7

Secondary: per-region detection rate

End point title	per-region detection rate

End point description:

Per-region detection rates will be analysed in the FAS in the same way as the per-patient detection rates.
The per-region detection rate will be defined as follows: number of patients defined as positive for a given region by the independent readers / total number of pateints assessde for a given region

End point type	Secondary

End point timeframe:

Overall study

End point values	18F-DCFPyL	18F-Fluorocholine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	201	201		
Units: percent				
prostate bed	21	11		
pelvic lymph nodes	29	25		
extra-pelvic lymph nodes	8	14		
bones	17	9		
other organs	9	2		

Statistical analyses

No statistical analyses for this end point

Secondary: sensitivity

End point title	sensitivity

End point description:

Number of true positive cases / True positive + false negative

End point type	Secondary

End point timeframe:

Overall study

End point values	18F-DCFPyL	18F-Fluorocholine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	205	205		
Units: percent	58	41		

Statistical analyses

Statistical analysis title	Chi squared
Comparison groups	18F-DCFPyL v 18F-Fluorocholine
Number of subjects included in analysis	410
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	≤ 0.001
Method	Chi-squared
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	1-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Any AE starting at the time or within the 24 hours following the start of injection (of 18F-DCFPyL or 18F-FCH) up to 48 h after injection.	
Adverse event reporting additional description:	
An event was considered as related to the study treatment if the relationship is ticked “Possible”, “Probable” or “Definite”.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups	
Reporting group title	full analysis set
Reporting group description:	
all patients having received at least one injection	

Serious adverse events	full analysis set		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 205 (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	full analysis set		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 205 (2.93%)		
Cardiac disorders			
Hypertension			
subjects affected / exposed	1 / 205 (0.49%)		
occurrences (all)	1		
Nervous system disorders			
headache			
subjects affected / exposed	2 / 205 (0.98%)		
occurrences (all)	2		
General disorders and administration site conditions			

Fatigue subjects affected / exposed occurrences (all)	1 / 205 (0.49%) 1		
Skin and subcutaneous tissue disorders Eczema subjects affected / exposed occurrences (all)	1 / 205 (0.49%) 1		
Musculoskeletal and connective tissue disorders Limb discomfort subjects affected / exposed occurrences (all)	1 / 205 (0.49%) 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

None reported