# 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<br>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<br>subjects affected / exposed<br>occurrences (all) | 1 / 205 (0.49%)<br>1 | | |
| Skin and subcutaneous tissue disorders<br>Eczema<br>subjects affected / exposed<br>occurrences (all) | 1 / 205 (0.49%)<br>1 | | |
| Musculoskeletal and connective tissue disorders<br>Limb discomfort<br>subjects affected / exposed<br>occurrences (all) | 1 / 205 (0.49%)<br>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