Clinical trial results:
PREFAcE - Interest of PET-PSMA imaging potentiated by androgen blockade in patients with biological relapse or persistent biological disease of a localized prostatic adenocarcinoma after initial treatment

Summary

EudraCT number	2019-003346-32
Trial protocol	FR
Global end of trial date	03 April 2024

Results information

Result version number	v1 (current)
This version publication date	27 May 2026
First version publication date	27 May 2026

Trial information

Trial identification

Sponsor protocol code	ET-19-194

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04391556
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Centre Léon Bérard
Sponsor organisation address	28 Rue Laënnec, Lyon, France,
Public contact	Médecine nucléaire, Centre Léon Bérard, +33 (0)478 78 26 82, severine.metzger@lyon.unicancer.fr
Scientific contact	Médecine nucléaire, Centre Léon Bérard, +33 (0)478 78 26 82, severine.metzger@lyon.unicancer.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	08 August 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 April 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Evaluate the potentiating effect of androgen blockade on the detection of prostate adenocarcinoma lesions by PSMA PET.

Protection of trial subjects:

No study-related procedure will be performed without prior written informed consent obtained from the patient. The investigator will inform the patient about the study treatment, its objectives, and its design, provide the patient information leaflet and informed consent form, answer any questions the patient may have, and ensure that the patient understands the potential risks and benefits of participating in the study before signing the informed consent form. Study treatments will be administered according to a predefined protocol-defined schedule of androgen deprivation therapy using degarelix (Firmagon®).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 September 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	France: 55
Worldwide total number of subjects	55
EEA total number of subjects	55

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)	18
From 65 to 84 years	37

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Inform the patient about the treatments, objectives, outcome and any ancillary studies, answer their questions and sign the informed consent with them after a reflection period . Check the eligibility criteria list and perform the exams (e.g. Physicial examination, baseline signs and symptoms...)

Period 1

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

Arms

Arm title	Preface study

Arm description:

This is a prospective cohort study in patients with biochemical recurrence or persistent biochemical disease of curatively treated prostate cancer, with each patient considered as their own control.

Arm type	Experimental
Investigational medicinal product name	Firmagon®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Injection

Dosage and administration details:

For each patient, a single injection of Firmagon®120 mg will be administered after the first PET-PSMA scan.

Number of subjects in period 1	Preface study
Started	55
Completed	44
Not completed	11
Physician decision	4
Patient's decision	7

Baseline characteristics

Reporting groups	
Reporting group title	Overall study period

Reporting group description: -

Reporting group values	Overall study period	Total	
Number of subjects	55	55	
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)	17	17	
From 65-84 years	38	38	
85 years and over	0	0	
Age continuous Units: years			
median	70		
full range (min-max)	49 to 81	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	55	55	

End points

End points reporting groups

Reporting group title	Preface study

Reporting group description:

This is a prospective cohort study in patients with biochemical recurrence or persistent biochemical disease of curatively treated prostate cancer, with each patient considered as their own control.

Primary: PET RESULTS between D1 1H and D14 1H

End point title	PET RESULTS between D1 1H and D14 1H[1]

End point description:

End point type	Primary

End point timeframe:

Comparison of the proportion of patients with a positive PET scan on initial PSMA-PET (before androgen blockade) and PSMA-PET-H (=PSMA-PET after androgen blockade) on standard pelvic acquisitions at 1 hour, with the patient serving as their own control.

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: At PET-PSMA on day 1 (1 hour), 22 patients were positive (50%) compared to 23 (52%) on day 14 (1 hour). The McNemar test showed no significant difference between the two time points (p = 0.317). 21 patients were negative at both examinations, 22 were positive at both, and 1 changed from negative to positive. Contrary to data in the literature (approximately 50% initial positivity expected and 70% at day 14), no increase in the positivity rate was observed.

End point values	Preface study			
Subject group type	Reporting group			
Number of subjects analysed	44			
Units: Patient				
number (not applicable)				
PET Result Positive D1 1h	22			
PET Result Positive D14 1h	23			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

The investigator collects (spontaneous patient report or questionning) and immediately notifies the sponsor of all SAEs, in a written report, wether or not theay are deemed to be attributable to research and wich occur during the study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

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: Thirty-nine patients (88.6%) experienced at least one adverse event (AE), with 9 patients (20.5%) experiencing at least one AE of grade ≥2 and no AEs of grade ≥3 reported. Thirty-nine patients (88.6%) experienced at least one AE related to Firmagon® and 8 patients (18.2%) of grade ≥2. No AEs related to PET/PSMA or Lasix were reported. One serious adverse event unrelated to Firmagon® was reported for patient 01-004: CORONAVIRUS INFECTION grade 1.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 December 2020	- Modification of two inclusion criteria to align with the French recommendations of the AFU Cancer Committee; - Modification of the acquisition time in the study objectives section. This acquisition time has been reduced from 3 hours to 2 hours ; - Removal of the secondary objective to study the reproducibility of the interpretation of the initial PSMA-PET and PSMA-H PET scans. Other modifications were made to the primary and secondary endpoints for greater clarity ; (ection VII (Statistical Considerations) has been modified due to the removal of the analysis of secondary endpoints.) - Clarification provided due to the power of the machines available at the centers ; - Update to the list of investigators (change of principal investigator)
30 March 2021	- Addition of brachytherapy given the therapeutic options for localized prostate adenocarcinomas; - Harmonization of the definition of biochemical recurrence (at least 2 biopsies in the last 12 months).
12 October 2021	- An 18-month extension of the recruitment period, a modification of the follow-up period, and consequently, an extension of the total study duration; - A modification of inclusion criterion I3 (removal of all imaging at inclusion); - A modification concerning the dose of Lasix®; - An update of the investigator list (addition of a new investigator and removal of investigators)
26 June 2023	- The extension of the inclusion period and the total duration of the study, without impacting the follow-up period ; - The opening of a new participating center

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported