



Clinical trial results:

Etude monocentrique, exploratoire, comparant la TEP/TDM au 68Ga-RM2 à la TEP/TDM au 68Ga-PSMA-617 chez des patients atteints de cancers de la prostate de différents risques métastatiques, candidats à une prostatectomie totale

Summary

EudraCT number	2017-000490-36
Trial protocol	FR
Global end of trial date	11 December 2020

Results information

Result version number	v1 (current)
This version publication date	18 September 2026
First version publication date	18 September 2026

Trial information

Trial identification

Sponsor protocol code	CHUBX2016/38
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03604757
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHU de Bordeaux
Sponsor organisation address	12 Rue Dubernat, Talence, France, 33404
Public contact	Dr Henri de CLERMONT-GALLERANDE, Service de Médecine Nucléaire, +33 0556795540, henri.de-clermont-galleran@chu-bordeaux.fr
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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	27 October 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 May 2020
Global end of trial reached?	Yes
Global end of trial date	11 December 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To compare 68Ga-PSMA-617 uptakes values between prostatic sextants for which histologic examination reveal a Gleason score 6, those for which histologic examination reveal a Gleason score 7(3+4) (favourable intermediate risk), for which histologic examination reveal a Gleason score 7(4+3) (unfavourable intermediate risk) and those for which histologic examination reveal a Gleason score 8 or more
- To compare 68Ga-RM2 uptakes values between prostatic sextants for which histologic examination reveal a Gleason score 6, those for which histologic examination reveal a Gleason score 3+4 (favourable intermediate risk), those for which histologic examination reveal a Gleason score 4+3 (unfavourable intermediate risk) and for which histologic examination reveal a Gleason score 8 or more

Protection of trial subjects:

There was no specific protection measure put in place in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2018
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: 22
Worldwide total number of subjects	22
EEA total number of subjects	22

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)	16
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

the recruitment phase started on April 25th 2018 and ended on April 25th 2020. Patients were included in one centre, the Bordeaux University Hospital.

Pre-assignment

Screening details:

The study included patients with newly diagnosed, biopsy-proven, prostate cancer

Other inclusion criteria were age greater than 18y, and indication for prostatectomy. No patient had received neoadjuvant hormone therapy or chemotherapy. All patients underwent extended pelvic lymph node dissection.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	68Ga-PSMA-617 PET/CT

Arm description:

68Ga-PSMA-617 PET/CT

Arm type	Experimental
Investigational medicinal product name	[68Ga]Ga-PSMA-617
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Radiopharmaceutical precursor, solution
Routes of administration	Injection

Dosage and administration details:

Using an automated synthesizer (GE FastLab, GE Healthcare, GEMS Benelux, Belgium), the 68Ge/68Ga generator (GalliAd®, IRE ELIT, Belgium, nominal activity 1850MBq at calibration date) was eluted with a sterile solution of hydrochloric acid (HCl) 0.1M in the reactor vial containing PSMA-617 (10 µg, GMP grade, ABX GmbH) or RM2 (40µg, GMP grade, Life Molecular Imaging).

In the case of RM2, 5mg of ascorbic acid were also added to prevent radiolysis. The reaction solution was heated at 90°C for 5 min using microwaves. The raw solution was then purified on a C18 cartridge (WAT023501) preconditioned with 1mL ethanol (Merck®) and 5 mL water (GE®). The final product was then formulated in sterile phosphate buffer saline and NaCl 0.9%, and filtered with a 0.22 µm filter.

Arm title	68Ga-RM2 PET/CT
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Arm description:

68Ga-RM2 PET/CT

Arm type	Active comparator
Investigational medicinal product name	68Ga-RM2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Radiopharmaceutical precursor, solution
Routes of administration	Injection

Dosage and administration details:

Using an automated synthesizer (GE FastLab, GE Healthcare, GEMS Benelux, Belgium), the 68Ge/68Ga generator (GalliAd®, IRE ELIT, Belgium, nominal activity 1850MBq at calibration date) was eluted with a sterile solution of hydrochloric acid (HCl) 0.1M in the reactor vial containing PSMA-617 (10 µg, GMP grade, ABX GmbH) or RM2 (40µg, GMP grade, Life Molecular Imaging).

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(WAT023501) preconditioned with 1mL ethanol (Merck®) and 5 mL water (GE®). The final product was then formulated in sterile phosphate buffer saline and NaCl 0.9%, and filtered with a 0.22 µm filter.

Number of subjects in period 1	68Ga-PSMA-617 PET/CT	68Ga-RM2 PET/CT
Started	11	11
Completed	11	11

Baseline characteristics

Reporting groups

Reporting group title	Overall study
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Reporting group description: -

Reporting group values	Overall study	Total	
Number of subjects	22	22	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
arithmetic mean	64		
standard deviation	± 5.9	-	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	22	22	
Gleason score			
Units: Subjects			
<6	5	5	
7 (3+4)	6	6	
7 (4+3)	4	4	
8 (4+4, 3+5, 5+3)	2	2	
>8	5	5	
TNM (T)			
Units: Subjects			
T2a	19	19	
T2c	3	3	
Body Mass Index			
Units: kilogram(s)/square metre			
arithmetic mean	27.4		
standard deviation	± 3.8	-	
Prostate Specific Antigen (PSA)			
Units: ng/mL			
arithmetic mean	8.3		
standard deviation	± 4	-	

End points

End points reporting groups

Reporting group title	68Ga-PSMA-617 PET/CT
Reporting group description:	68Ga-PSMA-617 PET/CT
Reporting group title	68Ga-RM2 PET/CT
Reporting group description:	68Ga-RM2 PET/CT

Primary: Maximum Standardized Uptake Value (SUV max) using 68Ga-PSMA-617 PET/CT or 68Ga-RM2 PET/CT

End point title	Maximum Standardized Uptake Value (SUV max) using 68Ga-PSMA-617 PET/CT or 68Ga-RM2 PET/CT
End point description:	
End point type	Primary
End point timeframe:	This is a diagnostic study where the primary endpoint is measured only once

End point values	68Ga-PSMA-617 PET/CT	68Ga-RM2 PET/CT		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	11		
Units: Standard Unit Value				
arithmetic mean (standard deviation)				
Gleason 6 (3+3)	3.26 ($\pm$ 1)	3.56 ($\pm$ 1.3)		
Gleason 7 (3+4)	3.79 ($\pm$ 0.97)	6.36 ($\pm$ 2.4)		
Gleason 7 (4+3)	6.33 ($\pm$ 1.08)	7.3 ($\pm$ 3.12)		
Gleason 8, 9 or 10	8.81 ($\pm$ 5.27)	6.58 ($\pm$ 3.06)		

Statistical analyses

Statistical analysis title	comparisons of Ga-PSMA-617 SUV between ISUP scores
Comparison groups	68Ga-PSMA-617 PET/CT v 68Ga-RM2 PET/CT
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	= 0.0025
Method	Mixed models analysis
Parameter estimate	percentage of variation

Notes:

[1] - Comparisons of SUVmax were performed at the cancer nodule level. All comparisons of SUVmax between ISUP scores used univariable mixed linear regression models including a random intercept to consider the intra-patient correlation (with a variance components structure). Model's hypotheses

(normality and heteroscedasticity of residuals) were systematically checked and led us to transform SUVmax values in pathologic tissues by the natural logarithm.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

UROPET was a transversal study. Only one day of participation for each patient.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	Whole study group
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Reporting group description: -

Serious adverse events	Whole study group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.01 %

Non-serious adverse events	Whole study group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 22 (4.55%)		
Vascular disorders			
Epistaxis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 October 2019	Extension of inclusion period for 6 months

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported