Clinical trial results:
68Ga-PSMA PET/CT vs. 18F-PSMA PET/CT for the diagnosis of metastases in newly diagnosed high-risk prostate cancer patients undergoing radical prostatectomy

Summary

EudraCT number	2021-004846-39
Trial protocol	DK
Global end of trial date	27 June 2024

Results information

Result version number	v1 (current)
This version publication date	13 November 2025
First version publication date	13 November 2025

Trial information

Trial identification

Sponsor protocol code	N-20200025

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aalborg University Hospital
Sponsor organisation address	Hobrovej 18-22, Aalborg, Denmark, 9000
Public contact	Department of Nuclear Medicine, Aalborg University Hospital, 0045 97665500, f.gossili@rn.dk
Scientific contact	Department of Nuclear Medicine, Aalborg University Hospital, 0045 97665500, f.gossili@rn.dk

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	01 October 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 June 2024
Global end of trial reached?	Yes
Global end of trial date	27 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary purpose of this study is to compare the diagnostic properties by the two PSMA-ligands (18F-PSMA PET/CT vs 68Ga-PSMA PET/CT) in patients undergoing radical prostatectomy.

Protection of trial subjects:

Patients underwent scanning by experienced personnel, with experience with clinical trials

Background therapy:

None

Evidence for comparator:

Histopathology of the surgical specimen served as reference standard.

Actual start date of recruitment	01 November 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 57
Worldwide total number of subjects	57
EEA total number of subjects	57

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	41
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were identified at the MDT conference and recruited from Department of Urology, Aalborg University Hospital

Pre-assignment

Screening details:

Consecutive men with high-risk prostate cancer, classified according to the D'Amico criteria and confirmed histologically as adenocarcinoma, were prospectively enrolled. Eligibility required no evidence of distant metastasis on conventional imaging and a planned radical prostatectomy, as determined by the prostate MDT-conference.

Pre-assignment period milestones

Number of subjects started	57
Number of subjects completed	50

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Consent withdrawn by subject: 7

Period 1

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

Arms

Arm title	Diagnostic crossover cohort

Arm description:

Study uses a crossover, paired design, there is no traditional "arm titles"

Arm type	Crossover, paired design
Investigational medicinal product name	MV09IX17
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solvent for solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

iv injection

Number of subjects in period 1[1]	Diagnostic crossover cohort
Started	50
Completed	50

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 57 were included , but 7 patients withdraw consent prior to the scan (which was a trial-specific scan)

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	50	50	
Age categorical			
18-64 years: 16 64-84 years: 41			
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)	40	40	
From 65-84 years	10	10	
85 years and over	0	0	
Age continuous			
Units: years			
geometric mean	70		
standard deviation	± 3	-	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	50	50	

Subject analysis sets

Subject analysis set title	overall trial
Subject analysis set type	Per protocol

Subject analysis set description:

Diagnostic crossover design, and patient were analysed pr. prtocol

Reporting group values	overall trial		
Number of subjects	50		
Age categorical			
18-64 years: 16 64-84 years: 41			
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)	40		
From 65-84 years	10		
85 years and over	0		
Age continuous			
Units: years			
geometric mean	70		
standard deviation	± 3		
Gender categorical			
Units: Subjects			
Female	0		
Male	50		

End points

End points reporting groups

Reporting group title	Diagnostic crossover cohort
Reporting group description:	
Study uses a crossover, paired design, there is no traditional “arm titles”	
Subject analysis set title	overall trial
Subject analysis set type	Per protocol
Subject analysis set description:	
Diagnostic crossover design, and patient were analysed pr. prtocol	

Primary: Diagnostic accuracy

End point title	Diagnostic accuracy[1]
End point description:	
Sensitivity, specificity, PPV, NPV of 18F-PSMA PET/CT vs 68Ga-PSMA PET/CT for detection of tumor in high-risk prostate cancer, using histopathology reference standards	
End point type	Primary
End point timeframe:	
finalized statistical analyses by 31st of Decemebr 2025	

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: Diagnostic accuracy in terms of sensitivity, specificity, PPV, NPV and accuracy

End point values	Diagnostic crossover cohort	overall trial		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	50	50		
Units: units	50	50		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
From the administration of the first study radiotracer dose until completion of prostatectomy	
Adverse event reporting additional description:	
SAEs/SUSARs within 24 hours, other AEs in periodic reports	
Assessment type	Systematic

Dictionary used	
Dictionary name	SNOMED CT
Dictionary version	2021

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

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: THis is a low intervention trial with a PET-tracer given in sub-physiologic amounts - thus absolutely no adverse events were seen in compliance with the reported litterature where more than 50.000 men have been investigated using this tracer

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