Clinical trial results:
PRISMA-PET – Primary Staging of Prostate Cancer: A Randomized Controlled Trial Comparing 18F-PSMA-1007 PET/CT to Conventional Imaging.

Summary

EudraCT number	2021-000123-12
Trial protocol	DK
Global end of trial date	21 January 2025

Results information

Result version number	v1 (current)
This version publication date	03 May 2026
First version publication date	03 May 2026

Trial information

Trial identification

Sponsor protocol code	2020110469

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05123300
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	Kløvervænget 47, Odense, Denmark, 5000
Public contact	Department of Nuclear Medicine, Odense University Hospital, +45 30171888, malene.grubbe.hildebrandt@rsyd.dk
Scientific contact	Department of Nuclear Medicine, Odense University Hospital, +45 30171888, malene.grubbe.hildebrandt@rsyd.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	22 January 2026
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 January 2025
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Men with a newly diagnosed intermediate or high risk (including locally advanced) prostate cancer or a clinical suspicion of
metastases based on other findings, and before any treatment is initiated.

Protection of trial subjects:

None

Background therapy:

None, this is an imaging tracer

Evidence for comparator:

Comparator is a clinically approved and used imaging tracer

Actual start date of recruitment	01 October 2021
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	20 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 385
Worldwide total number of subjects	385
EEA total number of subjects	385

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)	56

From 65 to 84 years	329
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were referred from departments of Urology for staging, and were offered inclusion if deemed eligible

Pre-assignment

Screening details:

As only relevant subjects were referred, screeening details are not available.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	NaF-PET/CT

Arm description:

Patients staged with NaF-PET/CT

Arm type	Active comparator
Investigational medicinal product name	Na[18F]F
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 MBq iv

Arm title	PSMA-PET

Arm description:

Patients staged with PSMA-PET

Arm type	Experimental
Investigational medicinal product name	[18F]PSMA-1007
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

2 MBq/kg, mininum 150 MBq and maximum 300 MBq.

Number of subjects in period 1	NaF-PET/CT	PSMA-PET
Started	192	193
Completed	186	188
Not completed	6	5
Consent withdrawn by subject	5	4

Not meeting the inclusion criteria	1	-
Didi not meet inclusion criteria	-	1

Baseline characteristics

Reporting groups	
Reporting group title	NaF-PET/CT
Reporting group description: Patients staged with NaF-PET/CT	
Reporting group title	PSMA-PET
Reporting group description: Patients staged with PSMA-PET	

Reporting group values	NaF-PET/CT	PSMA-PET	Total
Number of subjects	192	193	385
Age categorical			
Age at consent, information collected at inclusion			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	37	19	56
From 65-84 years	155	174	329
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	0	0	0
Male	192	193	385

Subject analysis sets	
Subject analysis set title	Progression free survival NaF vs PSMA
Subject analysis set type	Intention-to-treat
Subject analysis set description: data on progression / change of treatment regimen / death were registered and compared to the NaF-group	

Reporting group values	Progression free survival NaF vs PSMA		
Number of subjects	374		
Age categorical			
Age at consent, information collected at inclusion			
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)	56		
From 65-84 years	329		
85 years and over	0		
Gender categorical Units: Subjects			
Female	0		
Male	374		

End points

End points reporting groups

Reporting group title	NaF-PET/CT
Reporting group description: Patients staged with NaF-PET/CT	
Reporting group title	PSMA-PET
Reporting group description: Patients staged with PSMA-PET	
Subject analysis set title	Progression free survival NaF vs PSMA
Subject analysis set type	Intention-to-treat
Subject analysis set description: data on progression / change of treatment regimen / death were registered and compared to the NaF-group	

Primary: Progression free survival gr A vs gr B

End point title	Progression free survival gr A vs gr B[1]
End point description: time from inclusion to progression, relapse or death for any reason.	
End point type	Primary
End point timeframe: years	

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: The data analyzes have not been completed yet

End point values	NaF-PET/CT	PSMA-PET	Progression free survival NaF vs PSMA	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	186	188	374	
Units: 374				
Number of events	43	34	77	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
No adverse events reported	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	Redcap
Dictionary version	0

Reporting groups	
Reporting group title	NaF-PET
Reporting group description:	
Patients scanned with NaF-PET, the comparator	
Reporting group title	PSMA-PET
Reporting group description:	
Staged with PSMA-PET - the intervention	

Serious adverse events	NaF-PET	PSMA-PET	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 190 (0.00%)	0 / 192 (0.00%)	
number of deaths (all causes)	15	12	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	NaF-PET	PSMA-PET	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 190 (0.00%)	0 / 192 (0.00%)	

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: No adverse events were reported

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 March 2022	A maximum PSA level of 200 ng/ml was introduced as inclusion parametre

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Further data are to be collected, analyzed and reported

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/37636207

http://www.ncbi.nlm.nih.gov/pubmed/41290368