



## Clinical trial results:

**Randomized Assessment of patients with clinically suspected Prostate cancer after multiparametric metabolic hybrid Imaging to evaluate its potential clinical Domain:**

**A prospective, randomized, multi-arm, multi-treatment clinical trial**

### Summary

EudraCT number	2014-004758-33
Trial protocol	AT
Global end of trial date	01 May 2022

### Results information

Result version number	v1 (current)
This version publication date	08 April 2026
First version publication date	08 April 2026

### Trial information

#### Trial identification

Sponsor protocol code	Rapid-study
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#### Additional study identifiers

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

Notes:

### Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Prof. Marcus Hacker, Medical University of Vienna, marcus.hacker@meduniwien.ac.at
Scientific contact	Prof. Marcus Hacker, Medical University of Vienna, marcus.hacker@meduniwien.ac.at

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	12 November 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 May 2022
Global end of trial reached?	Yes
Global end of trial date	01 May 2022
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

We hypothesize that the image guided biopsy using multiparametric metabolic hybrid imaging with [18F]Fluoroethylcholine (FEC)/[68]Ga-PSMA-PET/MRI is superior in the detection of primary localized prostate cancer than the conventional biopsy approach with transrectal ultrasound in patients with suspected prostate cancer (according to the inclusion criteria) and could therefore significantly improve the detection rate of the dominant intraprostatic tumor lesion and reduce the number of biopsies needed for a correct histopathological diagnosis to a minimum in the future (PET/MRI guided biopsy).

Protection of trial subjects:

In this prospective randomized clinical trial including 220 men clinically suspicious of having prostate cancer, PSMA-targeted PET/MRI identified 91/113 histologically confirmed prostate cancers, 57/60 ISUP grade >2 tumors and predicted unfavorable disease in 23/25 patients in a median 3 years follow-up. 4-core PET/MRI-guided biopsy showed a comparable diagnostic efficacy as more invasive standard random biopsy. The results support the integration of this reliable imaging technique into clinical practice to improve the non-invasive diagnosis and prognostic categorization of prostate cancer, potentially reducing unnecessary biopsies and overtreatment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 January 2016
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	Austria: 220
Worldwide total number of subjects	220
EEA total number of subjects	220

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)	149
From 65 to 84 years	71
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Eligible participants were men with clinical signs suggestive of PCa, including elevated (.4.0 ng/mL) and progressively rising blood prostate-specific antigen (PSA) levels despite antibiotic treatment, or a free-to-total PSA ratio of less than 22%.

### Pre-assignment

Screening details:

Eligible participants were men with clinical signs suggestive of PCa, including elevated (.4.0 ng/mL) and progressively rising blood prostate-specific antigen (PSA) levels despite antibiotic treatment, or a free-to-total PSA ratio of less than 22%.

### Period 1

Period 1 title	active phase (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
Arm title	random biopsy Arm

Arm description:

The study randomly assigned patients (target of 220) to either the standard (random biopsy [RB]) group with a 12-core or greater standardized random needle biopsy (masked to PET/MRI results), or the image-guided biopsy (IGB) group, which involved the standardized 12-core needle biopsy plus 4 computer-assisted PET/MRI-guided targeted biopsies. An electronically generated randomization list was used to assign patients to each group after inclusion and exclusion criteria were checked for suitability by the principal investigator. All patients were to undergo multiparametric endorectal [18F]fluoroethylcholine PSMA PET/MRI.

Within 1 mo of imaging and randomization, patients were scheduled for RB or IGB, followed by an end-of-study visit within 2 wk or by surgery with an end-of-study visit. Follow-up visits were planned at 6, 12, 18, and 24 mo after the end-of-study visit. Further reporting on follow-up was performed voluntarily until the study closed on June 15, 2023.

Arm type	Active comparator
Investigational medicinal product name	18F fluoroethylcholine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

3MBq/kg Bodyweight

Investigational medicinal product name	68Ga PSMA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

2MBq/kg Bodyweight

Arm title	Image guided biopsy arm
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**Arm description:**

The study randomly assigned patients (target of 220) to either the standard (random biopsy [RB]) group with a 12-core or greater standardized random needle biopsy (masked to PET/MRI results), or the image-guided biopsy (IGB) group, which involved the standardized 12-core needle biopsy plus 4 computer-assisted PET/MRI-guided targeted biopsies. An electronically generated randomization list was used to assign patients to each group after inclusion and exclusion criteria were checked for suitability by the principal investigator. All patients were to undergo multiparametric endorectal [18F]fluoroethylcholine PSMA PET/MRI.

Within 1 mo of imaging and randomization, patients were scheduled for RB or IGB, followed by an end-of-study visit within 2 wk or by surgery with an end-of-study visit. Follow-up visits were planned at 6, 12, 18, and 24 mo after the end-of-study visit. Further reporting on follow-up was performed voluntarily until the study closed on June 15, 2023.

Arm type	Active comparator
Investigational medicinal product name	18F fluoroethylcholine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

**Dosage and administration details:**

3MBq/kg Bodyweight

Investigational medicinal product name	68Ga PSMA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

**Dosage and administration details:**

2MBq/kg Bodyweight

<b>Number of subjects in period 1</b>	random biopsy Arm	Image guided biopsy arm
Started	110	110
Completed	106	104
Not completed	4	6
Consent withdrawn by subject	-	1
contraindication for MRI	1	-
Biopsy refused	2	3
PSA control less than 4 ng/mL	-	1
Lost to follow-up	1	-
secondary cancer	-	1

## Baseline characteristics

### Reporting groups

Reporting group title	random biopsy Arm
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#### Reporting group description:

The study randomly assigned patients (target of 220) to either the standard (random biopsy [RB]) group with a 12-core or greater standardized random needle biopsy (masked to PET/MRI results), or the image-guided biopsy (IGB) group, which involved the standardized 12-core needle biopsy plus 4 computer-assisted PET/MRI-guided targeted biopsies. An electronically generated randomization list was used to assign patients to each group after inclusion and exclusion criteria were checked for suitability by the principal investigator. All patients were to undergo multiparametric endorectal [18F]fluoroethylcholine PSMA PET/MRI.

Within 1 mo of imaging and randomization, patients were scheduled for RB or IGB, followed by an end-of-study visit within 2 wk or by surgery with an end-of-study visit. Follow-up visits were planned at 6, 12, 18, and 24 mo after the end-of-study visit. Further reporting on follow-up was performed voluntarily until the study closed on June 15, 2023.

Reporting group title	Image guided biopsy arm
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#### Reporting group description:

The study randomly assigned patients (target of 220) to either the standard (random biopsy [RB]) group with a 12-core or greater standardized random needle biopsy (masked to PET/MRI results), or the image-guided biopsy (IGB) group, which involved the standardized 12-core needle biopsy plus 4 computer-assisted PET/MRI-guided targeted biopsies. An electronically generated randomization list was used to assign patients to each group after inclusion and exclusion criteria were checked for suitability by the principal investigator. All patients were to undergo multiparametric endorectal [18F]fluoroethylcholine PSMA PET/MRI.

Within 1 mo of imaging and randomization, patients were scheduled for RB or IGB, followed by an end-of-study visit within 2 wk or by surgery with an end-of-study visit. Follow-up visits were planned at 6, 12, 18, and 24 mo after the end-of-study visit. Further reporting on follow-up was performed voluntarily until the study closed on June 15, 2023.

Reporting group values	random biopsy Arm	Image guided biopsy arm	Total
Number of subjects	110	110	220
Age categorical			
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)	79	70	149
From 65-84 years	31	40	71
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	110	110	220

## End points

### End points reporting groups

Reporting group title	random biopsy Arm
Reporting group description: The study randomly assigned patients (target of 220) to either the standard (random biopsy [RB]) group with a 12-core or greater standardized random needle biopsy (masked to PET/MRI results), or the image-guided biopsy (IGB) group, which involved the standardized 12-core needle biopsy plus 4 computer-assisted PET/MRI-guided targeted biopsies. An electronically generated randomization list was used to assign patients to each group after inclusion and exclusion criteria were checked for suitability by the principal investigator. All patients were to undergo multiparametric endorectal [18F]fluoroethylcholine PSMA PET/MRI. Within 1 mo of imaging and randomization, patients were scheduled for RB or IGB, followed by an end-of-study visit within 2 wk or by surgery with an end-of-study visit. Follow-up visits were planned at 6, 12, 18, and 24 mo after the end-of-study visit. Further reporting on follow-up was performed voluntarily until the study closed on June 15, 2023.	
Reporting group title	Image guided biopsy arm
Reporting group description: The study randomly assigned patients (target of 220) to either the standard (random biopsy [RB]) group with a 12-core or greater standardized random needle biopsy (masked to PET/MRI results), or the image-guided biopsy (IGB) group, which involved the standardized 12-core needle biopsy plus 4 computer-assisted PET/MRI-guided targeted biopsies. An electronically generated randomization list was used to assign patients to each group after inclusion and exclusion criteria were checked for suitability by the principal investigator. All patients were to undergo multiparametric endorectal [18F]fluoroethylcholine PSMA PET/MRI. Within 1 mo of imaging and randomization, patients were scheduled for RB or IGB, followed by an end-of-study visit within 2 wk or by surgery with an end-of-study visit. Follow-up visits were planned at 6, 12, 18, and 24 mo after the end-of-study visit. Further reporting on follow-up was performed voluntarily until the study closed on June 15, 2023.	

### Primary: Superior cancer detection

End point title	Superior cancer detection
End point description: To demonstrate that multiparametric metabolic hybrid imaging with FEC/ PSMA-PET/MRI is superior in the detection of primary localized prostate cancer than the conventional biopsy approach (TRUS-guided) in patients with suspected prostate cancer (according to the inclusion criteria) and to significantly improve the detection rate of the dominant intraprostatic tumor lesion and reduce the number of biopsies needed for a correct histopathological diagnosis to a minimum in the future (PET/MRI guided biopsy).	
End point type	Primary
End point timeframe: Between February 5, 2016, and February 4, 2020	

End point values	random biopsy Arm	Image guided biopsy arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	110		
Units: percent	31	29		

### Statistical analyses

<b>Statistical analysis title</b>	Analysis primary endpoint
Comparison groups	random biopsy Arm v Image guided biopsy arm
Number of subjects included in analysis	220
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.05
Method	Chi-squared corrected



## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

Between February 5, 2016, and February 4, 2020

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.0
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Frequency threshold for reporting non-serious adverse events: 5 %

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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: There was no adverse events

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/41266255>