



Clinical trial results:

A 2 arm, phase II controlled randomized trial comparing efficacy and safety of abiraterone and abiraterone associated with Ablative Radiation Therapy in patients with Oligometastatic castration resistant prostate cancer (ARTO trial)

Summary

EudraCT number	2016-005284-13
Trial protocol	IT
Global end of trial date	10 September 2024

Results information

Result version number	v1 (current)
This version publication date	16 January 2025
First version publication date	16 January 2025
Summary attachment (see zip file)	Full published article (francolini-et-al-2023-stereotactic-body-radiation-therapy-and-abiraterone-acetate-for-patients-affected-by (2) (8).pdf)

Trial information

Trial identification

Sponsor protocol code	ARTO
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Dipartimento "Mario Serio" Univ. studi Firenze
Sponsor organisation address	Largo Brambilla 3, Florence, Italy,
Public contact	Data Manager, Dipartimento "Mario Serio" Univ. studi Firenze, +39 0557947192, datamanager.ng.rt@sbsc.unifi.it
Scientific contact	Data Manager, Dipartimento "Mario Serio" Univ. studi Firenze, +39 0557947192, datamanager.ng.rt@sbsc.unifi.it

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	10 September 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 September 2024
Global end of trial reached?	Yes
Global end of trial date	10 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary objective of the study will be PSA response >50% measured within 6 months.in nodal and/or bone oligometastatic (≤ 3 lesions), castration resistant prostate cancer patients undergoing SBRT in combination with AA (experimental arm), respect to patients treated with AA (control arm).

Protection of trial subjects:

The study was performed according to the Declaration of Helsinki principles. Informed consent to participate in the study was obtained from each enrolled patient.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 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	Italy: 157
Worldwide total number of subjects	157
EEA total number of subjects	157

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)	0
From 65 to 84 years	157
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Enrollment start in 2018 and ended in September 2022

Pre-assignment

Screening details:

None

Period 1

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

Blinding implementation details:

None

Arms

Are arms mutually exclusive?	Yes
Arm title	Control

Arm description:

Abiraterone alone

Arm type	Active comparator
Investigational medicinal product name	Abiraterone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1000 mg day

Arm title	Treatment
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Arm description:

Abiraterone+SBRT

Arm type	Experimental
Investigational medicinal product name	Abiraterone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1000 mg day

Number of subjects in period 1	Control	Treatment
Started	82	75
Completed	82	75

Baseline characteristics

End points

End points reporting groups

Reporting group title	Control
Reporting group description: Abiraterone alone	
Reporting group title	Treatment
Reporting group description: Abiraterone+SBRT	

Primary: Biochemical response

End point title	Biochemical response
End point description: The difference between the two arms in terms of biochemical response (BR) rate (defined as percentage of patients with a PSA decrease $\geq 50\%$ compared with baseline) at 6 months after AAP treatment start was the primary end point of the trial	
End point type	Primary
End point timeframe: 6 months	

End point values	Control	Treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	75		
Units: Nr of patients	55	69		

Statistical analyses

Statistical analysis title	Statistical analysis
Statistical analysis description: The distribution of categorical and continuous variables was compared between the control and the treatment arms by means of Fisher's exact and Wilcoxon's rank sum tests, respectively. The effect of the arm allocation (experimental v control) and baseline covariates (baseline PSA for each increase by 1 ng/mL, the number of metastatic sites 1 v >1, restaging at enrollment with PSMA/fluciclovine PET v every other method, presence of bone metastasis v nodal only disease, and de novo metastat	
Comparison groups	Control v Treatment

Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

January 2018- September 2024

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	2.1
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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: Adverse events are reported in the published article

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