



## Clinical trial results: 18FDHT-PET to visualize the effect on the androgen receptor level by bicalutamide

### Summary

EudraCT number	2015-001634-17
Trial protocol	NL
Global end of trial date	25 November 2019

### Results information

Result version number	v1 (current)
This version publication date	25 May 2022
First version publication date	25 May 2022
Summary attachment (see zip file)	Paper trial results (2021 EJC Boers serial FDHT PET to predict bicalutamide effect.pdf)

### Trial information

#### Trial identification

Sponsor protocol code	2015.0704
-----------------------	-----------

#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02697032
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	University Medical Center Groningen
Sponsor organisation address	Hanzeplein 1, Groningen, Netherlands,
Public contact	Department of Medical Oncology, University Medical Center Groningen, +31 503616161, c.p.schroder@umcg.nl
Scientific contact	Department of Medical Oncology, University Medical Center Groningen, +31 503616161, c.p.schroder@umcg.nl

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	18 December 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	25 November 2019
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Feasibility to detect a difference in uptake on 18F-FDHT scan after 4 weeks of treatment with bicalutamide in metastatic breast cancer patients.

Protection of trial subjects:

no specific measures

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2017
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	Netherlands: 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)	11
From 65 to 84 years	11
85 years and over	0

## Subject disposition

### Recruitment

#### Recruitment details:

Patients will be recruited both from the academic center as well as regional hospitals. The patients will be informed by one of the investigators under the supervision of the PI. Patients will be informed with a patient letter and have a week to consider. The written informed consent form should be signed and personally dated by the patient

### Pre-assignment

#### Screening details:

25 pts signed consent, of which 2 screenfailures and in 1 patient baseline FDHT-PET was performed, but was not treated with bicalutamide. In addition, another patient was treated short-term with bicalutamide and underwent 2x FDHT-PET, however metastasis biopsy showed HER2+, so bicalutamide was discontinued. 21 patients will be included for analysis

### 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	patients
-----------	----------

#### Arm description:

At day 0 before start with bicalutamide, a FDHT-PET/CT will be performed, and one after 6 weeks (i.e. 2 weeks after steady-state). The second FDHT-PET will be performed to determine if this scan can be used as a biomarker for early response. Patients will be treated with bicalutamide until progression or unacceptable toxicity is encountered.

Arm type	Experimental
Investigational medicinal product name	Bicalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

#### Dosage and administration details:

150 mg milligram(s) per day buccal use

Investigational medicinal product name	16-beta-[18F]fluoro-5-alpha-dihydrotestosterone
Investigational medicinal product code	18F-FDHT
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

#### Dosage and administration details:

up to 200 MBq

<b>Number of subjects in period 1</b>	patients
Started	22
Completed	22

## Baseline characteristics

### Reporting groups

Reporting group title	overall trial
-----------------------	---------------

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	22	22	
Age categorical			
adults			
Units: Subjects			
Adults (18-64 years)	11	11	
From 65-84 years	11	11	
85 years and over	0	0	
Age continuous			
adults			
Units: years			
median	65		
standard deviation	± 11	-	
Gender categorical			
Units: Subjects			
Female	22	22	
Male	0	0	

## End points

### End points reporting groups

Reporting group title	patients
Reporting group description: At day 0 before start with bicalutamide, a FDHT-PET/CT will be performed, and one after 6 weeks (i.e. 2 weeks after steady-state). The second FDHT-PET will be performed to determine if this scan can be used as a biomarker for early response. Patients will be treated with bicalutamide until progression or unacceptable toxicity is encountered.	

### Primary: Quantify residual AR binding sites in metastatic breast cancer

End point title	Quantify residual AR binding sites in metastatic breast cancer <sup>[1]</sup>
End point description: To quantify residual AR binding sites in metastatic breast cancer after 6 weeks of treatment with bicalutamide.	
End point type	Primary
End point timeframe: 6 weeks	
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: see enclosed publication	

End point values	patients			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: SUV	22			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Determine changes in 18F-FDHT uptake

End point title	Determine changes in 18F-FDHT uptake
End point description: To determine whether changes in 18F-FDHT uptake after 6 weeks associates with response to bicalutamide.	
End point type	Secondary
End point timeframe: 6 weeks	

<b>End point values</b>	patients			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: SUV	22			

## Statistical analyses

No statistical analyses for this end point

### Secondary: Influence amount of AR tumor expression

End point title	Influence amount of AR tumor expression
End point description:	To determine whether 18F-FDHT tracer uptake is influenced by the amount of AR tumor expression.
End point type	Secondary
End point timeframe:	6 weeks

<b>End point values</b>	patients			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: SUV	22			

## Statistical analyses

No statistical analyses for this end point

### Secondary: Difference in changes in AR availability

End point title	Difference in changes in AR availability
End point description:	To determine whether changes in AR availability are different for breast cancer subgroups during treatment with bicalutamide
End point type	Secondary
End point timeframe:	6 weeks

<b>End point values</b>	patients			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: SUV	22			

### Statistical analyses

---

No statistical analyses for this end point

## Adverse events

---

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

---

Timeframe for reporting adverse events:  
during study

---

Adverse event reporting additional description:

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to FDHT-PET scan or the treatment of bicalutamide. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

---

Assessment type	Systematic
-----------------	------------

---

### Dictionary used

---

Dictionary name	Toetsing online
Dictionary version	1

---

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: see enclosed publication

## 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

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

described in article
----------------------

Notes:

---

### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/33341447>