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-alphadihydrotestosterone
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

Number of subjects in period 1	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[1]

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

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: 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

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: 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

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

Adverse events

Adverse events information[1]

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 investiga¬tor 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