Clinical trial results:
HER2-PET as a diagnostic tool in breast cancer patients with a clinical dilemma

Summary

EudraCT number	2012-003789-41
Trial protocol	NL
Global end of trial date	14 October 2015

Results information

Result version number	v1 (current)
This version publication date	12 October 2022
First version publication date	12 October 2022

Trial information

Trial identification

Sponsor protocol code	Her2.5

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01832051
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Medical Center Groningen
Sponsor organisation address	Hanzeplein 1, Groningen, Netherlands, 9713 GZ
Public contact	CP. Schröder, University Medical Center Groningen, 0031 503612821, c.p.schroder@umcg.nl
Scientific contact	CP. Schröder, University Medical Center Groningen, 0031 503612821, 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	14 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 October 2015
Global end of trial reached?	Yes
Global end of trial date	14 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to assess the contribution of HER2-PET to subsequent anti-HER2-therapy decisions, in patients suspected of metastatic or locally recurrent HER2-positive breast cancer, with a clinical dilemma defined as failure of standard work up to evaluate the HER2 receptor status of their disease.

Protection of trial subjects:

To gain additional information on which adjustment of anti-HER2 therapy might be based, patients will make 4 extra visits to the clinic, including blood sampling, tracer injection and a HER2-PET scan implementing a radiation burden of approximately 20 mSv.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 July 2013
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	Netherlands: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	19
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening visit
- Screening of patient, informed consent, collection of information
- Collection of patient characteristics, physical examination
- Blood sampling for routine hematology and biochemistry; for women of childbearing potential a pregnancy test will be performed

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	HER2-PET

Arm description:

Injection of 89Zr-trastuzumab followed by PET scan

Arm type	Experimental
Investigational medicinal product name	89Zr-SUCDF-trastuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

1 Ci curie(s) total

Number of subjects in period 1	HER2-PET
Started	20
Completed	20

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	20	20	
Age categorical Units: Subjects			
Adults (18-64 years)	19	19	
From 65-84 years	1	1	
Gender categorical Units: Subjects			
Female	20	20	

End points

End points reporting groups

Reporting group title	HER2-PET

Reporting group description:

Injection of 89Zr-trastuzumab followed by PET scan

Primary: Concordance between HER2-PET results and anti-HER2 therapy

End point title	Concordance between HER2-PET results and anti-HER2

End point description:

Concordance between HER2-PET results and anti-HER2 therapy is defined as HER2 positive lesion(s) on HER2-PET and subsequent anti-HER2 therapy; or no HER2 positive lesions on HER2-PET and no subsequent anti-HER2 therapy. It is considered a clinically relevant contribution of HER2-PET to anti-HER2-therapy decisions if there is a concordance in at least 2/3 of included patients.

End point type	Primary

End point timeframe:

about 2 years (end of study)

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: descriptive statistics

End point values	HER2-PET			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: SUV	20			

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of HER2-PET results and questionnaire results regarding clinical value of HER2-PET for the referring clinician

End point title	Correlation of HER2-PET results and questionnaire results regarding clinical value of HER2-PET for the referring clinician

End point description:

Correlation of HER2-PET result (assessed about 1 week after scan) and questionnaire results (before, directly after, and 3 months after scan)

End point type	Secondary

End point timeframe:

about 2 years (end of study)

End point values	HER2-PET			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: SUV	20			

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of HER2-PET results with standard conventional work-up

End point title	Correlation of HER2-PET results with standard conventional work-up

End point description:

Correlation of HER2-PET result (assessed about 1 week after scan) and standard conventional work-up (assessed before/at screening)

End point type	Secondary

End point timeframe:

about 2 years (end of study)

End point values	HER2-PET			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: SUV	20			

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of HER2-PET results and HER-2 expression by CTCs

End point title	Correlation of HER2-PET results and HER-2 expression by CTCs

End point description:

Correlation of HER2-PET result (assessed about 1 week after scan) and HER-2 expression by CTCs (blood for CTC analysis will be drawn at day of tracer injection, analysis within 3 days)

End point type	Secondary

End point timeframe:

about 2 years (end of study)

End point values	HER2-PET			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: SUV	20			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: within 15 days after the sponsor has first knowledge of the adverse reactions.	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4

Frequency threshold for reporting non-serious adverse events: 2 %

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 observed

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 January 2014	new version IMPD, administrative change patient information
10 November 2014	- update participating center - update cold dose Trastuzumab - Update IMPD 89Zr-sucDF-trastuzumab

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30058029