Clinical trial results:
Phase II study evaluating the toxicity and activity of the combination lapatinib + capecitabine in elderly patients aged 70 and over with metastatic breast cancer over expressing HER2

Summary

EudraCT number	2009-015981-73
Trial protocol	FR
Global end of trial date	12 November 2013

Results information

Result version number	v1 (current)
This version publication date	23 September 2022
First version publication date	23 September 2022

Trial information

Trial identification

Sponsor protocol code	GERICO 09/0907

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01262469
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Unicancer
Sponsor organisation address	101 rue de Tolbiac, Paris, France, 75013
Public contact	Nourredine AIT-RAHMOUNE, Unicancer, +33 171936704, n.ait-rahmoune@unicancer.fr
Scientific contact	Nourredine AIT-RAHMOUNE, Unicancer, +33 171936704, n.ait-rahmoune@unicancer.fr

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 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 November 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess clinical benefit (defined at 4 months as complete response, partial response or stable disease), safety and preserved geriatric independence. (main objective is a "bi-criteria" or composite criteria).

Protection of trial subjects:

In order to ensure the protection of the rights, safety and well-being of trial subjects, this study was conducted in accordance with the ethical principles that have their origins in the latest version of the Declaration of Helsinki (1964) and subsequent amendments, ICH Good Clinical Practice Guidelines (CPMP/ICH/135/95), the European Directive (2001/20/CE) on the conduct of clinical trials, and the applicable local regulatory requirements and laws (The Huriet Law N°88-1138 of the 20th December 1998 on the protection of persons taking part in biomedical research; The National Informatics and Freedoms Commission – Law N° 78-17 of the 6th January 1978 modified by the law N° 2004-801 of the 6th August 2004 concerning the protection of the person with regards to the use of personal data; Bioethical law N°2011-814 of the 8th July 2011).
Furthermore, independent Ethics Committees reviewed and gave favorable opinions to the study documents, including the initial protocol and all subsequent amendments, and all information and documents provided to subjects/patients.
Written informed consent was obtained from all patients prior to enrollment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 May 2010
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	France: 4
Worldwide total number of subjects	4
EEA total number of subjects	4

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	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The GERICO 09 study was a multicentric phase II study evaluating the toxicity and activity of the combination of lapatinib+ capecitabine in locally advanced or metastatic breast cancer over expressing HER2 for patients aged ≥70 who have failed after one line of chemotherapy in combination with trastuzumab.

Pre-assignment

Screening details:

The study consisted of a 28-day screening phase (patients' eligibility and baseline measurements), a treatment phase (21-day cycle till disease progression or unacceptable toxicity), and a long-term follow-up to monitor the clinical benefit rate, time to progression, progression-free survival, overall survival, overall response, rate and safety

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Lapatinib plus capecitabine

Arm description:

Lapatinib was administrated orally at the dose of 1250 mg/day in combination with capecitabine. Capecitabine was administered at 850 mg/m² bi-daily from D1 to D14 of the first 21-cycle then, if no unacceptable toxicity was observed during the first cycle, at the dose of 1000 mg/m² bi-daily from D1 to D14 of subsequent 21-day cycles.

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

Dosage and administration details:

1250 mg/day, one hour before breakfast.

Investigational medicinal product name	Capecitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

First 21-day cycle: 850 mg/m² bi-daily from D1 to D14 during a meal (or within 30 minutes after), at breakfast and dinner.
Subsequent 21-day cycles: 1000 mg/m² bi-daily from D1 to D14 during a meal (or within 30 minutes after), at breakfast and dinner.

Number of subjects in period 1	Lapatinib plus capecitabine
Started	4
Completed	0
Not completed	4
Disease progression	2
Adverse event, non-fatal	2

Baseline characteristics

Reporting groups	
Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	4	4	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	4	4	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	4	4	
Male	0	0	

End points

End points reporting groups

Reporting group title	Lapatinib plus capecitabine

Reporting group description:

Lapatinib was administrated orally at the dose of 1250 mg/day in combination with capecitabine. Capecitabine was administered at 850 mg/m² bi-daily from D1 to D14 of the first 21-cycle then, if no unacceptable toxicity was observed during the first cycle, at the dose of 1000 mg/m² bi-daily from D1 to D14 of subsequent 21-day cycles.

Primary: Clinical benefit

End point title	Clinical benefit[1]

End point description:

End point type	Primary

End point timeframe:

Benefit was defined at 4 months after inclusion as complete response, partial response, or stable disease.

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: The study was halted prematurely with only 4 patients inlcuded. Thus, no statistical analysis was performed.

End point values	Lapatinib plus capecitabine			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: percent				
number (not applicable)				

Notes:

[2] - Due to early termination of the study with only 4 patients included, no analysis was performed

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Overall period of the study (up to 2.5 years after inclusion)	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	12
Reporting groups	
Reporting group title	Lapatinib plus capecitabine

Reporting group description: -

Serious adverse events	Lapatinib plus capecitabine		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Lapatinib plus capecitabine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)		
Nervous system disorders			
Neuromuscular disorders			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Hemoglobin			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	5		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)		
occurrences (all)	9		
Gastrointestinal disorders			

Anorexia subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 5		
Constipation subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Diarrhoea subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 9		
Pain abdominal subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Dyspepsia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Mucositis subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Nausea subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 3		
Gastroesophageal reflux subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Vomiting subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Hepatobiliary disorders Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 4		
Palmar-plantar erythrodysaesthesia syndrome			

subjects affected / exposed occurrences (all)	3 / 4 (75.00%) 8		
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	 1 / 4 (25.00%) 3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 January 2010	The inclusion criteria number 9 was modified. The minimum hemoglobin level was set up at 10 g/dl (instead of 9 g/dl) with this amendment.
18 February 2011	The inclusion criteria #7 was amended to allow for the recruitment of patients who would not have received trastuzumab.

Notes:

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.

The study was stopped prematurely due to lack of recruitment (4 patients included.

Notes: