LUX-Breast 1; An open label, randomised phase III trial of BIBW 2992 and vinorelbine versus trastuzumab and vinorelbine in patients with metastatic HER2-overexpressing breast cancer failing one prior trastuzumab treatment

Published: 21-04-2010
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To investigate the efficacy and safety of BIBW 2992 in combination with vinorelbine iv chemotherapy as treatment in patients with HER2-overexpressing, metastatic breastcancer, who failed one prior trastuzumab treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON34674

Source
ToetsingOnline

Brief title
LUX-Breast 1

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer, mammacarcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Boehringer Ingelheim

Intervention

Keyword: breastcancer, EGFR/HER2 inhibitor, trastuzumab, vinorelbine

Outcome measures

Primary outcome

The primary endpoint of this study is progression free survival, defined as the time from the date of randomisation to the date of disease progression, or to the date of death if a patient died earlier.

Secondary outcome

Secundary endpoints:

- overall survival;
- best RECIST assesment;
- safety;
- tumour shrinkage;
- maintenance of bodyweight;
- ECOG performance status;
- incidence of brain metastases;
- health related quality of life;
- pharmokinetics of BIBW 2992.

Study description

Background summary

An open label, randomised phase 3 trial of BIBW 2992 and vinorelbine versus trastuzumab and vinorelbine in patients with metastatic HER2-overexpressing breast cancer failing one prior trastuzumab treatment.

Study objective

To investigate the efficacy and safety of BIBW 2992 in combination with vinorelbine iv chemotherapy as treatment in patients with HER2-overexpressing, metastatic breastcancer, who failed one prior trastuzumab treatment.

Study design

Open-label, randomised phase 3 study, 2;1 randomisation

Intervention

One group receives oral BIBW once daily and intravenously vinorelbine. The other group receives weekly intravenous trastuzumab and weekly intravenuosly vinorelbine.

Study burden and risks

Considering the estimated mean of 9 months (described at question E2) the burden is:
physical examination: 11x
HRQOL questionnaire 11x
ECG: 5x
LVEF echo or MUGA: 4x
bloodwithdrawal: 39x
CT or MRI scan: 6x
Administration of studymedication per infusion: 9x

Contacts

Public
Boehringer Ingelheim

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- female patients, older than 18;
- Histologically confirmed diagnosis of HER2 overexpression breast cancer;
- Stage 4 metastatic disease;
- Progressed on one prior trastuzumab treatment, but not received and failed on more than 1 trastuzumab based treatment;
- Patient must have received anthracycline and/or taxane based chemotherapy for adjavant treatment or first line treatment;
- Must have (archived) tumour tissue sample available for central re-assessment of HER2 status and prove HER2 positive;
- Must have at least one measurable lesion according to the RECIST criteria;
- Must have an ECOG score of 0 or 1;
- Must have a life expectancy of at least 6 months.

Exclusion criteria

- Prior treatment with EGFR/HER2 targeted small molecules or antibodies other than trastuzumab;
- Prior treatment with vinorelbine;

- Known pre-existing interstitial lung disease;
- Radiotherapy, chemotherapy, hormone therapy, immunotherapy or surgery (other than biopsy) within 4 weeks prior to randomisation;
- Active brain metastases;
- Any other current malignancy or malignancy diagnosed within the last 5 years;
- Significant or recent acute gastro-intestinal disorders;
- History or presence of clinically relevant cardiovascular abnormalities;
- Cardiac left ventricular function with less than 50%.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Herceptin
Generic name:	Trastuzumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Navelbine

Generic name:	Vinorelbine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-04-2010
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	17-05-2010
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	17-06-2010
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	21-10-2010
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	19-04-2011
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	21-10-2011
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	12-03-2012
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	11-05-2012
Application type:	Amendment

Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	20-08-2012
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	20-12-2012
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	10-06-2013
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	01-11-2013
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	29-08-2014
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-015476-98-NL
CCMO	NL31076.096.10