HOMERUS: A LOCAL, OPEN LABEL, MULTICENTRE, PHASE IIIB STUDY, INVESTIGATING SUBCUTANEOUS TRASTUZUMAB ADMINISTERED AT HOME WITH SINGLE INJECTION DEVICE IN PATIENTS WITH HER2-POSITIVE EARLY BREAST CANCER

Published: 24-09-2013
Last updated: 25-04-2024

The primary objective of this study is to assess the overall safety and tolerability of subcutaneous (SC) trastuzumab using SID (Singel Injection Device) in HER2-positive eBC (early Breast Cancer) patients self-administered at home under supervision...

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

Summary

ID

NL-OMON47299

Source
ToetsingOnline

Brief title
HOMERUS

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, HER-2 positive breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Roche Nederland B.V.
Source(s) of monetary or material Support: Roche Nederland B.V.

Intervention

Keyword: Breast cancer, HER-2, Subcutaneous ('Single Injection Device'), Trastuzumab

Outcome measures

Primary outcome

Primary Objective

The primary objective of this study is to assess the overall safety and

tolerability of subcutaneous (SC) trastuzumab using SID in HER2-positive eBC

patients self-administered at home under supervision of trained HCP.

Secondary outcome

Secondary Objectives

The secondary objectives of this study are PK analysis of self-administration

at home, patient reported outcomes and proportion of patients choosing to

return to hospital administration.

Exploratory Objective

To assess efficacy (disease-free survival and overall survival data)

Study description

Background summary

Breast cancer is the most commonly diagnosed cancer (23% of all cancers) and the leading cause of cancer death in women worldwide. Studies have shown that women whose tumours exhibit either amplification of the HER2 gene or overexpression of its encoded protein have a more aggressive form of breast cancer that is associated with significantly shortened disease-free (DFS) and overall survival (OS) compared with women whose tumours do not over express HER2. Trastuzumab (Herceptin) is a humanized monoclonal antibody directed against the extracellular domain of HER2. It is indicated for the treatment of patients with HER2-positive MBC and EBC and HER2-positive metastatic gastric cancer. The efficacy and safety of intravenous (IV) trastuzumab have been well characterized. Subcutaneous administration of trastuzumab takes significantly less time (up to 5 minutes) compared to IV infusion (30 to 90 minutes) and this is expected to improve treatment convenience and compliance. Trastuzumab SC is een new route of administration and might provide the oppertunity of administration of trastuzumab outside the hospital and optimize the ease, costs and compliace for patients in the near future.

Study objective

The primary objective of this study is to assess the overall safety and tolerability of subcutaneous (SC) trastuzumab using SID (Singel Injection Device) in HER2-positive eBC (early Breast Cancer) patients self-administered at home under supervision of trained HCP (health care professional).

Study design

The study is a single arm phase IIIb, open label, local multicenter study to assess the safety and tolerability of trastuzumab solution injected subcutaneously with a single injection device (SID) in patients with Her2-positive eBC, following surgery and chemotherapy (neo-adjuvant or adjuvant).

Patients will receive a fixed dose of 600 mg trastuzumab SC throughout the study, administered 3-weekly for up to a total of 1 year trastuzumab, unless disease recurrence, unacceptable toxicity or patient withdrawal necessitates earlier treatment cessation. The first three study treatment administrations will occur in a hospital setting, following administrations will occur at home unless patient chooses to go back to hospital administration. This choice will be offered to patients after three administrations at home.

Patients are asked to come to the hospital for the screening / baseline visit and then for 5 visits during the treatment period, a safety follow-up visit 4 weeks after the last study treatment and every 6 months (up to 24 months after the safety follow up visit)

Intervention

The investigational medicinal product for this study is trastuzumab SC 600 mg, supplied as a SID formulation.

Patients in this local study will receive a fixed dose of 600 mg trastuzumab SC throughout the study, administered 3-weekly up to a total of 18 cycles/1 year trastuzumab, unless disease recurrence, unacceptable toxicity or study withdrawal necessitates earlier treatment cessation.

Trastuzumab SC via SID will be administered at hospital by a HCP for first 3 cycles, patients will be trained for self-administration.

Trastuzumab SC via SID will be administered at home for the following cycles, once adequately trained, patient are permitted to self-administer the injection supervised by a HCP.

Concurrent curative radiotherapy or anti-hormone therapy will be allowed as per institutional guidelines.

SID: a ready-to-use automated injection device containing 600 mg/5 ml trastuzumab

Study burden and risks

The following study-specific actions are extra compared to the standard treatment as stated in the SPC text for the transtuzumab treatment: Screening:
* Pregnancytest in blood (if the patient is a woman of childbearing potential). This test should be performed within 7 days prior to the first treatment with trastuzumab. Additional pregnancy tests (urine) should be preformed if clinically indicated during the study treatment and for 7 months after the last dose of study drug. Positive urine pregnancy tests should be confirmed by serum pregnancy test.
* Registration of demographic information, medical history and (if needed) medication.
* Assessment of cardiac function (including ECG)
* Withdrawal of about 20ml blood for standard laboratory tests.
* ECOG.

During the period of study treatment the patient will receive up to 18 treatments (for up to 12 months): every 3 weeks 1 trastuzumab treatment is given unless the patient has unacceptable side effects or if the cancer is recurrent (in which case the study treatment will be discontinued) .
The following actions will take place during the treatment period:
* Monitoring of vital signs with each administration.
* Cycle 1, 5, 9, 13 and/or the last treatment cycle: ECOG, weight, physical examination, assessment of cardiac function, discussion of health status and medication use.
* At 1st, 9th and last cycle, additional blood samples will be taken for

standard laboratory tests (approximately 20 ml)
* At cycle 1, 3, 9, 10 or 13, blood withdrawal to determine the amount of trastuzumab in the blood (approximately 2 ml)
* At cycle 3 and 9 a questionnaire will be completed.

The following assessments will take place during the follow-up visits:
* Monitoring of vital signs, physical examination and determination of the weight.
* ECOG.
* Evaluation of cardiac function (including ECG and ECHO or MUGA).
* Standard follow-up for breast cancer.
* Discussion of health, including possible side effects (adverse medical events) that may have occurred since the last trastuzumab has been administered.
* Discussion of medication.
* Collection of blood samples for standard laboratory tests.
* Every 6 months contact for health and well-being. This follow-up takes at least up to 24 months.

Contacts

Public
Roche Nederland B.V.

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NL
Scientific
Roche Nederland B.V.

Beneluxlaan 2a
Woerden 3446 GR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Female and male patients aged * 18 years
2. Eastern Cooperative Oncology Group (ECOG) performance status 0*1
3. Hormonal therapy will be allowed as per institutional guidelines
4. Prior use of anti-HER2 therapy in combination with chemotherapy will be allowed
5. Left ventricular ejection fraction (LVEF) of * 50% measured by echocardiography (ECHO) or multiple gated acquisition (MUGA) scan prior to first dose of trastuzumab SC, or, for those who were receiving trastuzumab when beginning the study, documented results within an acceptable limit from a cardiac assessment within 3 months prior to enrolment.Except in case patient received anthracycline treatment previously then documented results within an acceptable limit from a cardiac assessment within 14 days prior to enrolment.
6. HER2-positive disease immunohistochemistry (IHC)3+ or in situ hybridization (ISH) positive as determined in a local laboratory that is experienced/certified in HER2-expression testing using an accurate and validated assay
7. Histologically confirmed non-metastatic primary invasive adenocarcinoma of the breast
8. No evidence of residual, locally recurrent or metastatic disease after completion of surgery and chemotherapy, or during concurrent chemotherapy (neo-adjuvant or adjuvant)
9. Use of concurrent curative radiotherapy will be permitted
10. Completion of surgery and chemotherapy (if applicable) for eBC

Exclusion criteria

1. History of other malignancy which could affect compliance with the protocol or interpretation of results.
2. Patients with severe dyspnea at rest or requiring supplementary oxygen therapy
3. Patients with other concurrent serious diseases that may interfere with planned treatment
4. Serious cardiac illness or medical conditions that would preclude the use of trastuzumab
5. Pregnant or lactating women.
6. Women of childbearing potential (premenopausal or less than 12 months of amenorrhea post-menopause, unless surgically sterile), and male patients with partners of childbearing potential who are unable or unwilling to use adequate contraceptive measures during study treatment. In this study, menopause is defined as a minimum of 12 consecutive months of amenorrhea during which time no other biological or physiological cause had been identified as a potential cause of this state. Examples of adequate contraceptive measures are intrauterine device, barrier method (condoms, diaphragm) also in conjunction with spermicidal jelly, or total abstinence. Oral, injectable, or implant hormonal contraceptives are not acceptable

7. Concurrent enrolment in another clinical trial using an investigational anti-cancer treatment, including hormonal therapy, bisphosphonate therapy and immunotherapy, within 28 days prior to the first dose of study treatment
8. Known hypersensitivity to trastuzumab, murine proteins, to any of the excipients of Herceptin® including hyaluronidase, or the adhesive of the SC device, or a history of severe allergic or immunological reactions
9.Patients assessed by the investigator to be unable or unwilling to comply with the requirements of the protocol
10. Impaired hepatic function
11. Inadequate renal function

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2014
Enrollment:	125
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Herceptin SC (with single use injection device)
Generic name:	trastuzumab SC (with single use injection device)
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Herceptin SC (with vial)
Generic name:	trastuzumab SC

Ethics review

Approved WMO Date:	24-09-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-10-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-12-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-12-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-02-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	24-02-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-05-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-08-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-08-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-06-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-07-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-01-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-10-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	05-12-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-06-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-07-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2013-000829-31-NL
CCMO	NL44120.056.13
Other	wordt geregistreerd op www.clinicaltrials.gov