Long-term safety of trastuzumab in patients with HER2-positive breast cancer

Published: 14-10-2009
Last updated: 10-08-2024

Primary objective • To explore changes in left ventricular ejection fraction (LVEF) values before, during and after trastuzumab treatment Secondary objectives• To explore the reversibility of congestive heart failure associated with trastuzumab...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON33506

Source
ToetsingOnline

Brief title
Long-term safety of trastuzumab

Condition

- Heart failures
- Miscellaneous and site unspecified neoplasms benign

Synonym
decrease of left ventricular ejection fraction

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: eigen middelen onderzoeksgroep

Intervention

Keyword: - HER2 positive breast cancer, - long-term safety, - trastuzumab

Outcome measures

Primary outcome

- Left ventricular ejection fraction (LVEF)

Secondary outcome

- NT-proBNP en troponin T analysis

- New York Heart Association (NYHA)

- genotype analysis

- electrocardiogram

Study description

Background summary

Patients with HER2-positive breast cancer receive one year of trastuzumab as part of optimal standard adjuvant systemic therapy. The addition of trastuzumab to the standard adjuvant chemotherapy in HER2-positive breast cancer patients markedly improves treatment outcome. Short-term side effects of trastuzumab treatment are mild and mostly treatable. Few long-term data are available of trastuzumab tolerability. In this study we want to recruit long-term breast cancer survivors after adjuvant trastuzumab treatment to participate in a late tolerability study, to determine long-term effects after trastuzumab treatment to added co morbidity over time.

Study objective

Primary objective
• To explore changes in left ventricular ejection fraction (LVEF) values before, during and after trastuzumab treatment

Secondary objectives
• To explore the reversibility of congestive heart failure associated with trastuzumab treatment
• To determine the relation between *Brain Natriuretic Peptide* (NT-proBNP),

troponin T blood levels and changes in left ventricular ejection fractions (LVEF) after trastuzumab treatment
• To determine genetic variability in relevant known single nucleotide polymorphisms [SNPs] in the extracellular-, transmembrane and intracellular domain

Study design

Retrospective part (period before and during trastuzumab treatment) and a prospective part (period after trastuzumab treatment) of the study

Study burden and risks

Three hospital visits will be done during the first- and during the second study period. In one session five tubes of 5 ml blood will be taken for haematological, chemistry and genotype analysis. The following assessments will be performed; MUGA scan and electrocardiogram.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Strongly HER2-positive breast cancer, defined as an immunohistochemistry score of 3+ using the HercepTestTM, or gene amplification by fluorescence in situ hybridization, or chromogenic in situ hybridization (CISH)

Exclusion criteria

Pregnancy or breast feeding

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	14-10-2009
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
CCMO	NL27175.031.09