RANDOMIZED PHASE II/III STUDY OF SECOND-LINE ENDOCRINE TREATMENT FOLLOWED BY CAPECITABINE VERSUS CAPECITABINE FOLLOWED BY ENDOCRINE TREATMENT IN PATIENTS WITH METASTATIC ER POSITIVE BREAST CANCER

Published: 27-12-2007
Last updated: 10-05-2024

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

Summary

ID

NL-OMON31795

Source
ToetsingOnline

Brief title
Capecitabine vs hormonal treatment

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mammary neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breast cancer, ER positive, metastatic, PD after/during 1st line hormonal therapy

Outcome measures

Primary outcome

Primary endpoints :

Quality of life during the study period

- Physical functioning scale of the QLQ-C30

- Global Health status/QoL of the QLQ-C30

Secondary outcome

Secondary endpoint:

The EQ-5D Health State Summary Score

The EQ-5D VAS Score

Time to second progression and quality of life adjusted time

to 2nd recurrence.

Time to progression after first intervention.

Overall survival

Study description

Background summary

It is commonly accepted that the treatment of patients with metastatic disease which is hormone receptor positive, should be as long as possible with a treatment with endocrine agents, deferring toxic chemotherapy to a later point in time. As a result, many patients with ER-positive disease receive subsequent lines of hormonal agents.
Several chemotherapeutic agents that have significant single agent activity have become available that are associated with relatively little toxicity. One of these is capecitabine, an antimetabolite that can be viewed as a fluorouracil prodrug. Capecitabine can be taken orally and has acceptable toxicity.
Earlier use of capecitabine in this group of patients may be more favourable.

Study objective

This trial studies the effects on quality of life and on time to second progression of the sequence endocrine therapy-capecitabine versus the sequence capecitabine-endocrine treatment. It is anticipated that the time on study (which is the time between randomization and the discontinuation of the second treatment in the sequence) will be similar for both arms of the study. The quality of life during this period, however, could be better in the patient group receiving the most effective first agent in the sequence. If this proves to be true, the conventional wisdom that endocrine therapy should be continued until no further endocrine options remain, must be abandoned.

Study design

This is a randomized phase II/II studie. Patients are randomized for the sequence capecitabine-hormonal therapie versus hormonal therapy- capecitabine. At progression the patient should receive the other protocol treatment (e.g. if the patient was randomized to capecitabine, at progression the treatment should be switched to hormonal treatment).

Intervention

Assigned protocol treatment is to be continued until progression (either clinical or documented by radiology). At progression the patient should receive the other protocol treatment (e.g. if the patient was randomized to capecitabine, at progression the treatment should be switched to hormonal treatment).
At progression of disease after the second treatment the patient will be taken off study
Patients will be seen on the out patient clinic every 6 weeks.
During the treatment patients will be asked to complete two quality of life forms every six weeks. Also at start of the second protocol treatment patient will be asked to complete the quality of life forms.

Therapy is given according to the hospital standard.

Study burden and risks

During treatment patients will be seen on the out patient clinic every 6 weeks. At this visit hematology and chemistry laboratory tests will be performed. During the treatment patients will be asked to complete two quality of life forms every six weeks. Also at start of the second protocol treatment patient will be asked to complete the quality of life forms

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

1. Written informed consent.
2. Proven infiltrating breast cancer with distant metastases or inoperable locally advanced disease.
3. Positive estrogen receptor (>= 10% positive nuclei at immunohistochemistry). Progesteron and HER-2 neu receptor have to be known.
4. - Progressive disease during first line hormonal therapy (either tamoxifen or aromatase inhibitor) for metastatic or inoperable locally advanced disease. Simultaneous use of LH-RH analogs is allowed.
OR
- Recurrence of disease (M1) during adjuvant hormonal therapy (either tamoxifen or aromatase inhibitor).
5. No prior chemotherapy for metastatic disease
6. Willing and able to participate in Quality of Life investigation

Exclusion criteria

1. Other malignancy except carcinoma in situ, unless the other malignancy was treated 5 or more years ago with curative intent without the use of chemotherapy or radiation therapy.
2. Pregnancy or breast feeding women.
3. Contra-indications to the use of capecitabine
4. Known CNS metastases

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2008

Enrollment:	128
Type:	Actual

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Aromasin
Generic name:	Exemestane
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Femara
Generic name:	Letrozole
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tamoxifen
Generic name:	Tamoxifen
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xeloda
Generic name:	Capecitabine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-12-2007
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
EudraCT	EUCTR2007-007030-20-NL
CCMO	NL20922.031.07