# 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

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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

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| 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 |

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| Enrollment: | 128 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| 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

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|---|---|
| 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 |