# Investigation on the Duration of Extended Adjuvant Letrozole treatment.

Gepubliceerd: 22-09-2011 Laatst bijgewerkt: 18-08-2022

To investigate whether 5 years of extended adjuvant treatment with letrozole results in an improved DFS compared to 2.5 years treatment in patients with early breast cancer previously treated with endocrine agents for 5 years.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON23112

**Bron**
NTR

**Verkorte titel**
IDEAL

**Aandoening**

breast cancer, post-menopausal, aromatase inhibitor, letrozole, extended hormonal therapy
mamma carcinoom, aromatase remmer, verlengde hormonale therapie

### Ondersteuning

**Primaire sponsor:** Leiden University Medical Center (LUMC)
**Overige ondersteuning:** Novartis (unrestricted educational grant)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Disease free survival (DFS).

# Toelichting onderzoek

### Achtergrond van het onderzoek

There is scientific evidence that it is beneficial to start using letrozole after having received tamoxifen for 5 years, even if tamoxifen was stopped a considerable time ago. Whether this is also true for other adjuvant treatment schedules like 5 years of an aromatase inhibitor or a sequence strategy with tamoxifen is unclear. The MA.17 trial reported that letrozole was safe and well tolerated.

Based on the above, there seems to be a good scientific rationale to investigate whether longer duration of extended adjuvant treatment with letrozole improves DFS compared to shorter duration in patients with early breast cancer, who have had adjuvant endocrine treatment for 5 years and have completed treatment for no longer than 2 years.

### Doel van het onderzoek

To investigate whether 5 years of extended adjuvant treatment with letrozole results in an improved DFS compared to 2.5 years treatment in patients with early breast cancer previously treated with endocrine agents for 5 years.

### Onderzoeksopzet

63 events diagnosed after 2.5 years for interim analysis.

126 events diagnosed after 2.5 years for final analysis.

### Onderzoeksproduct en/of interventie

1. 2.5 years letrozole;

2. 5 years letrozole.

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Postmenopausal at the time of randomization;

2. Histologically proven invasive breast cancer (stage I, II, or III) adequately treated at the time of diagnosis;

3. ER and/or PgR positive breast cancer;

4. Completed 5 year (± 3 months) adjuvant endocrine therapy with either tamoxifen for 5 years, aromatase inhibitors for 5 years or a sequence of both (provided that tamoxifen was given upfront for 2-3 years);

5. No evidence of breast cancer recurrence including contralateral breast cancer at the time of randomization;

6. WHO performance status 0, or 1;

7. Adjuvant endocrine treatment completed for no longer than 2 years (with a tolerance window of 3 months);

8. Accessible for follow-up for the duration of the trial;

9. Written informed consent.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. ER and PgR negative or unknown primary tumors;

2. Evidence of previous or current localized or distant breast cancer recurrence;

3. Bilateral breast cancer and/or (preventive) bilateral mastectomy;

4. Untreated hyperlipidemia (total cholesterol ≥ 7.75 mmol/L, triglycerides ≥ 2.5 x ULN);

5. Concurrent use of other aromatase inhibitors;

6. Concurrent chemotherapy;

7. Any use of HRT or SERMS. Patients on HRT and willing to participate in the trial will have to discontinue HRT 4 weeks prior to randomization. Topical estrogens are discouraged during the trial;

8. Previous or concomitant malignancy within the past 5 years (except adequately treated basal or squamous cell carcinoma of the skin or CIS of the cervix). Patients with a malignancy in their history more than 5 years ago must be disease free at least for 5 years. Patients with a history of breast cancer, other than the breast cancer under study are always excluded;

9. Other non-malignant systemic diseases including uncontrolled infections, uncontrolled DM-II, uncontrolled thyroid dysfunction, cardiovascular, renal, hepatic, and lung diseases, which would prevent prolonged follow-up. Patients with previous history of thrombosis or thromboembolism can be included only if medically suitable;

10. Patients with a known history of HIV;

11. Severe concomitant physical or psychological diseases that might impair compliance or assessment of drug/patient safety, e.g. clinically significant ascites, cardiac failure, NYHA III or IV, clinically relevant pathologic findings in ECG;

12. Uncontrolled seizure disorders associated with falls;

13. Patients treated with systemic investigational drug(s) and/or device(s) within the past 30 days or topical investigational drugs within the past 7 days;

14. History of non-compliance to medical treatment and patients considered potentially unreliable;

15. Mental illness that precludes the patient from giving informed consent.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 02-04-2007 |
| Aantal proefpersonen: | 1823 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 22-09-2011 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2930 |
| NTR-old | NTR3077 |
| Ander register | BOOG : 2006-05 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A