Investigation on the Duration of Extended Adjuvant Letrozole treatment.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23112

Source
NTR

Brief title
IDEAL

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Novartis (unrestricted educational grant)

Intervention

Outcome measures

Primary outcome

Disease free survival (DFS).

Secondary outcome

1. Overall survival;

2. Distant disease free survival;

3. Contralateral breast cancer;

4. Safety.

Study description

Background summary

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.

Study objective

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.

Study design

63 events diagnosed after 2.5 years for interim analysis.

126 events diagnosed after 2.5 years for final analysis.

Intervention

1. 2.5 years letrozole;

2. 5 years letrozole.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-04-2007
Enrollment:	1823
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-09-2011
Application type:	First submission

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
NTR-new	NL2930
NTR-old	NTR3077
Other	BOOG : 2006-05
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A