Tamoxifen and Exemestane Adjuvant Multicenter trial.

Gepubliceerd: 08-09-2005 Laatst bijgewerkt: 18-08-2022

Alternative hypothesis is that the HR is 1.28 for relapse free survival for the first 2¾ years.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22587

Bron
Nationaal Trial Register

Verkorte titel
TEAM

Aandoening

Breast cancer.

Ondersteuning

Primaire sponsor: Erasmus Medical Center - Daniel den Hoed Cancer Center
P.O. Box 5201
3008 AE ROTTERDAM
Overige ondersteuning: Pfizer (unrestricted educational grant)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Relapse Free Survival (RFS) at 2¾ years.

Toelichting onderzoek

Achtergrond van het onderzoek

Study rationale:

The good antitumor activity and safety profile of exemestane, as demonstrated in the phase II and III studies in postmenopausal women with metastatic breast cancer provide a good rationale to investigate the efficacy and safety of adjuvant exemestane in a prospective, randomised study versus the current standard tamoxifen, in postmenopausal women with ER positive early breast cancer.

Intervention:

Subjects will be randomized 1:1 to receive either exemestane (25 mg once daily) for 5 years or tamoxifen (20 mg once daily) for 2½-3 years followed by 2½-2 years of exemestane (25 mg once daily).

Primary objective:

To determine whether up-front adjuvant treatment with exemestane compared with adjuvant tamoxifen improves the relapse-free survival (RFS) of postmenopausal, receptor positive, early breast cancer patients following 2¾ (2½ -3) years of treatment.

Key secondary objective:

5-years RFS.

Other secondary endpoints:

Overall survival, the relative safety profiles, and the incidence of new primary breast cancers of.

Side studies:

1. Life style;

2. Cognitive function;

3. Bone mineral density;

4. Translational research.

Doel van het onderzoek

Alternative hypothesis is that the HR is 1.28 for relapse free survival for the first 2¾ years.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Subjects will be randomised 1:1 to receive either exemestane, 25 mg once daily for 5 years or tamoxifen 20 mg once daily for 2½-3 years followed by 2½ -2 years of exemestane 25 mg once daily, for a total of 5 years.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Histologically/cytologically confirmed adenocarcinoma of the breast, followed by intended curative surgery (R0) and if indicated, also radiotherapy;

2. Any Tumor with a size > 3 cm, or Any N+ or tumor size 1-3 cm, N0 and one of the following factors: MAI > 10, Bloom-Richardson: grade 3, Any TNM stage BC considered to receive adjuvant hormonal therapy, as agreed by NABON-NVMO;

3. ER and/or PgR receptor status positive;

4. Post-menopausal defined as:

a. Age ³ 50 and amenorrhea for > 1 year;

b. Bilateral surgical oophorectomy (and no HRT) (any age is acceptable);

c. Age < 50 with natural amenorrhea > 1 year at breast cancer diagnosis (and uterus in situ) In case of doubt about subject's menopausal status, FSH assessments have to be performed to define the menopausal status (FSH should be in the postmenopausal range according to values of the local institution);

5. Adequate hematological-, renal- and hepatic function (defined as PLT > 100x109/L, WBC > 3x 10 9/L, Creatinine< 1.5 UNL and SGOT (ASAT) or SGPT (ALAT) < 2.5 UNL);

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

7. ECOG performance status 0 or 1;

8. Written informed consent (according to ICH/GCP and local IRB guidelines);

9. Baseline clinical laboratory tests are done within 4 weeks prior to randomization;

10. Adjuvant hormonal treatment is started within 10 weeks after completion of surgery (date of tumor removal or re-excision) or date of last adjuvant chemotherapy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Inflammatory breast cancer, positive supraclavicular nodes, ulceration/infiltration of local skin metastasis;

2. Both ER negative and PgR negative primary tumor;

3. Evidence of distant metastases (M1);

4. Patients who have received previous hormonal treatment as adjuvant treatment for breast cancer;

5. Uncontrolled cardiac disease including unstable angina, CHF or arrhythmia requiring medical therapy or with a history of myocardial infarction within the past 3 months or any other serious concomitant disease.;

6. Psychiatric disorders preventing proper informed consent;

7. Tumor with a size < 1cm and N0;

8. Tumor size 1-3 cm, N0 without additional risk factors;

9. Concomitant malignancies except for adequately treated carcinoma in situ of the uterine cervix or basal squamous cell carcinoma of the skin, unless agreed by the Steering Committee. Subjects with other malignancies must be disease-free for at least 5 years. Patients with a history of breast cancer should be excluded;

10. Concurrent participation in another clinical study that may interfere with the results of the trial involving investigational agents within thirty days of treatment from this study, unless this is agreed by both the Steering Committee and the Coordinating Investigator of the study involved;

11. Other serious illnesses that may interfere with subject compliance, adequate informed consent or determination of causality of adverse events;

12. Hormone replacement therapy for treatment of menopausal symptoms that was not stopped at least 4 weeks prior to randomization;

13. Patients who were treated with neo-adjuvant chemotherapy;

14. Patients with a bilateral tumor.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2001
Aantal proefpersonen:	9000
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2005
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	NL230
NTR-old	NTR267
Ander register	: BOOG-01
ISRCTN	ISRCTN75225940

Resultaten

Samenvatting resultaten
N/A