Immediate optimal endocrine adjuvant therapy versus standard chemotherapy followed by the same endocrine therapy in pre- or perimenopausal patients with early hormone receptor-positive breast cancer the PROMISE study.

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To compare the efficacy and tolerability of immediate optimal endocrine adjuvant therapy versus standard chemotherapy (5 endocrine therapy in pre- and perimenopausal patients with ER and/or PR courses FE90C) followed by the same positive primary...

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

Samenvatting

ID

NL-OMON25775

Bron
NTR

Verkorte titel
PROMISE, BOOG 2002-01

Aandoening

breast cancer

Ondersteuning

Primaire sponsor: BOOG
Overige ondersteuning: CKTO
AstraZeneca

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Relapse-free survival (RFS).

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

To compare the efficacy and tolerability of immediate optimal endocrine adjuvant therapy versus standard chemotherapy (5 endocrine therapy in pre- and perimenopausal patients with ER and/or PR courses FE90C) followed by the same positive primary breast cancer.

Onderzoeksproduct en/of interventie

arm A: goserelin + anastrozole for 5 years (experimental arm)

B: 5 courses of FEC90 followed by goserelin + anastrozole for 5 years
Goserelin is available as 4-weeks depot (Zoladex 3.6 mg) and as 3-month depot (Zoladex 10.8 mg). Zoladex 3.6 mg depot will be administered subcutaneously every 28 days.
The Zoladex 10.8 mg depot will be administered every 12 weeks.
Anastrozole 1 mg/day
FEC90 (standard dose, day 1, every 21 days):

- Cyclophosphamide 500 mg/m2 i.v. (push)

- Epidoxorubicine 90 mg/m2 i.v. (push)

- 5-Fluorouracil 500 mg/m2 i.v. (push)

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1.. Pre-/perimenopausal patients aged less than 60 years at entry of the trial. Patients must have had their last menstrual period less than 2 years before surgery of the primary tumor. In previously hysterectomised patients, women with both postmenopausal plasma FSH and estradiol concentrations will be excluded;

2.
a. Any N+ subgroup (N1-3, N4-9, N□10);
b. Any high-risk N0 subgroup which meets one of the following criteria:

b1. Tumor size >= 3 cm;

b2 Tumor size 2-3 cm with grade II or III;

b3.Tumor size 1-2 cm with grade III;

b4. Patients < 35 years of age (with exception in case of tumors ≤ 1 cm, grade I);

3. ER or PgR receptor status positive as defined by local hospital criteria (as cut-off levels are adviced minimally >= 10% positively staining tumor cell by immunohistochemistry or >= 10 fmol/mg protein by ligand binding assay). ER-positive, PgR-negative patients are eligible;

4. Patients with either Her2/neu negative or positive tumors are eligible;

5. No previous systemic therapy for breast cancer;

6. 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);

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

8.ECOG performance status 0 or1 (appendix II);

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Those patients who did not undergo intended curative primary treatment or who fulfilled one of the following criteria:

1. Inflammatory breast cancer;

2. Positive supraclavicular nodes;

3. Ulceration/infiltration of local skin metastasis;

4. Primary surgery was completed more than 12 weeks before starting the randomised treatment;

5. Both ER negative and PgR negative primary tumor;

6. Evidence of distant metastases (M1);

7. Patients who have received previous systemic endocrine and/or chemotherapeutic treatment for breast cancer;

8. 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;

9. Psychiatric disorders preventing proper informed consent;

10. Tumor with a size < 1cm and N0 and age > 35 years;

11. Tumor size 1-2 cm, N0 with grade I or II and age > 35 years;

12. Tumor size 2-3 cm, N0 with grade I and age > 35 years;

13. 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;

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

15. Patients who are using contraceptive pills or receiving any HRT for treatment of peri-/postmenopausal symptoms should stop taking these endocrine agents at least 4 weeks prior to randomization;

16. Pregnancy or breast feeding;

17. In case a germline BRCA1 or BRCA2 mutation is known in the family of the patient, it is adviced not to include such patient in the study because of the different management of these patients and the increased risks of contralateral breast cancer and ovarian cancer (it is not warranted to perform standardly a DNA-test within the context of this trial).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2005
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
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	NL319
NTR-old	NTR357
Ander register	: N/A
ISRCTN	ISRCTN23561723

Resultaten

Samenvatting resultaten

N/A