

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

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/08/2006	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

PROMISE, BOOG 2002-01

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Breast cancer

Interventions

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

B: 5 courses of FEC90 followed by goserelin + anastrozole for five years

Goserelin is available as four weeks depot (Zoladex 3.6 mg) and as three 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 intravenously (iv) (push), Epirubicin 90 mg/m² iv (push), 5-Fluorouracil 500 mg/m² iv (push)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Goserelin, anastrozole

Primary outcome measure

Relapse-free survival (RFS)

Secondary outcome measures

1. Overall survival (OS), the incidence of contralateral breast cancer
2. Safety and longterm tolerability of both treatment regimens

Overall study start date

01/07/2005

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. Pre-/peri-menopausal patients aged less than 60 years at entry of the trial. Patients must have had their last menstrual period less than two years before surgery of the primary tumor. In previously hysterectomised patients, women with both post-menopausal plasma Follicle Stimulating Hormone (FSH) and estradiol concentrations will be excluded.

1.a. Any N+ subgroup (N1-3, N4-9, N10)

b. Any high-risk N0 subgroup which meets one of the following criteria:

i. Tumor size more than or equal to 3 cm

ii. Tumor size 2-3 cm with grade II or III

iii. Tumor size 1-2 cm with grade III

iv. Patients under 35 years of age (with exception in case of tumors less than or equal to 1 cm, grade I)

3. Estradiol Receptors (ER) and Progesterone Receptors (PgR) status positive as defined by local hospital criteria (as cut-off levels are advised minimally more than or equal to 10% positively staining tumor cell by immunohistochemistry or more than or equal to 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 more than $100 \times 10^9/l$, white blood cell count (WBC) more than $3 \times 10^9/l$, Creatinine less than 1.5 Upper Normal Limit (UNL) and SGOT (Aspartate Aminotransferase [AST]) or SGPT (Alanine Aminotransferase [ALT]) less than 2.5 UNL)
7. Accessible for follow-up for the duration of the trial
8. Eastern Cooperative Oncology Group (ECOG) performance status zero or one
9. Written informed consent (according to International Conference on Harmonisation [ICH] /Good Clinical Practice [GCP] and local Institutional Review Board [IRB] guidelines)

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

25

Key exclusion criteria

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, Chronic Heart Failure (CHF) or arrhythmia requiring medical therapy or with a history of myocardial infarction within the past three months or any other serious concomitant disease
9. Psychiatric disorders preventing proper informed consent
10. Tumor with a size less than 1cm and N0 and age more than 35 years
11. Tumor size 1-2 cm, N0 with grade I or II and age over 35 years
12. Tumor size 2-3 cm, N0 with grade I and age over 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 five 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 Hormone Replacement Therapy (HRT) for treatment of peri-/post-menopausal symptoms should stop taking these endocrine agents at least four weeks prior to randomisation

16. Pregnancy or breast feeding

17. In case a germline BRCA1 or BRCA2 mutation is known in the family of the patient, it is advised not to include such patients 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 Deoxyribonucleic Acid (DNA) test within the context of this trial)

Date of first enrolment

01/07/2005

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

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Sponsor information

Organisation

Breast Cancer Study Group (BOOG) (The Netherlands)

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Sponsor type

Not defined

ROR

<https://ror.org/04cr37s66>

Funder(s)

Funder type

Industry

Funder Name

CKTO, Astra Zeneca

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration