ISRCTN23561723 https://doi.org/10.1186/ISRCTN23561723

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

Submission date
19/12/2005

Recruitment status
No longer recruiting

Registration date
19/12/2005

Overall study status
Completed

Last Edited
24/08/2006

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof J.G.M. Klijn

Contact details
Erasmus Medical Center
Daniel den Hoed Kliniek
Department of Medical Oncology
P.O. Box 5201
Rotterdam
Netherlands
3008 AE
+31 (0)10 4391733
j.g.m.klijn@erasmusmc.nl

Additional identifiers

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

Study type(s)
Treatment

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/m^2 intravenously (iv) (push), Epidoxorubicine 90 mg/m^2 iv (push), 5-Fluorouracil 500 mg/m^2 iv (push)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Goserelin, anastrozole

Primary outcome(s)
Relapse-free survival (RFS)

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

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 x 10^9/l, white blood cell count (WBC) more than 3 x 10^9/l, Creatinine less than 1.5 Upper Normal Limit (UNL) and SGOT (Aspartate Aminotransferase [AST]) or SGPT (Alanine Aminotrasferase [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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
3008 AE

Sponsor information

Organisation
Breast Cancer Study Group (BOOG) (The Netherlands)

ROR
https://ror.org/04cr37s66

Funder(s)

Funder type
Industry

Funder Name
CKTO, Astra Zeneca

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration