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Ovarian Protection Trial In Oestrogen Non-responsive premenopausal breast cancer patients receiving adjuvant or neo-adjuvant chemotherapy

Submission date
21/01/2004

Recruitment status
No longer recruiting

Registration date
10/03/2004

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-ovarian-protection-for-premenopausal-women-having-chemotherapy-for-breast-cancer

Study website
http://www.lifesci.sussex.ac.uk/pog/option.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-000133-11

IRAS number

ClinicalTrials.gov number
NCT00427245

Secondary identifying numbers
BR 0301

Study information

Scientific Title
Ovarian Protection Trial In Oestrogen Non-responsive premenopausal breast cancer patients receiving adjuvant or neo-adjuvant chemotherapy

Acronym
OPTION

Study objectives
Goserelin may help prevent early menopause in patients undergoing chemotherapy for breast cancer. It is not yet known whether goserelin is effective in preventing early menopause in women undergoing chemotherapy for 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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Breast Cancer

Interventions
Treatment A: Chemotherapy
Treatment B: Chemotherapy plus Goserelin

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Rate of premature menopause, defined as cessation of menses during a course of chemotherapy with no recovery for at least 12 months.

Secondary outcome measures
1. Incidence of menopausal symptoms
2. Quality of life
3. Bone mineral density loss as measured by dual energy X-ray absorptiometry scans at 12, 24, and 36 months and by serum biomarkers
4. Hormone levels (including follicle-stimulating hormone, luteinizing hormone, beta-inhibin, and estradiol) as measured after course three, after course six or eight (depending on chemotherapy regimen), at 9 and 12 months, and then annually for up to five years
5. Menstruation history as measured by patient menstrual diary for 24 months from the start of chemotherapy
6. Incidence of pregnancy

Overall study start date
01/01/2004

Completion date
31/12/2004

Eligibility

Key inclusion criteria
Disease characteristics:
1. Histologically confirmed invasive breast cancer
2. Stages I-IIIB with node-positive or -negative disease (N0-2)
3. Operable disease
4. Must meet one of the following criteria:
4.1. Has undergone mastectomy or breast-conserving surgery with complete excision of primary tumor within the past eight weeks
4.2. Scheduled to receive neoadjuvant chemotherapy
4.3. No metastatic breast cancer, including supraclavicular fossa metastases

4.4. Hormone receptor status meeting one of the following criteria:
4.4.1. Estrogen receptor (ER) and progesterone receptor poor or negative AND not a candidate for adjuvant endocrine therapy
4.4.2. ER positive AND no requirement for ovarian suppression as a necessary part of treatment

Patient characteristics:
1. Female
2. Premenopausal with regular menses in the 12 months preceding surgery
3. No other prior or concurrent invasive malignancy except adequately treated basal cell or squamous cell skin cancer or carcinoma in situ of the cervix
4. Suitable fitness status for chemotherapy
5. Adequate hepatic, renal, and bone marrow function
6. Not pregnant or nursing
7. Fertile patients must use effective contraception

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
400

Total final enrolment
227

Key exclusion criteria
Prior chemotherapy or endocrine therapy.

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Singleton Hospital
Swansea

United Kingdom
SA2 8AQ

Sponsor information

Organisation
Clinical Trials Advisory and Awards Committee (CTAAC) (UK)

Sponsor details
Cancer Research UK
PO Box 123
London
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Sponsor type
Research organisation

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Research organisation

Funder Name
Clinical Trials Advisory and Awards Commitee (CTAAC) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016	08/02/2019	Yes	No
Plain English results			26/10/2022	No	Yes