

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

<b>Submission date</b> 21/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/03/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> 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>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

ClinicalTrials.gov (NCT)

NCT00427245

## Clinical Trials Information System (CTIS)

2004-000133-11

### Protocol serial number

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

### Study type(s)

Treatment

### 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(s)**

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

### **Key secondary outcome(s)**

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

### **Completion date**

31/12/2004

## **Eligibility**

### **Key inclusion criteria**

Disease characteristics:

1. Histologically confirmed invasive breast cancer
2. Stages I-III B 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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Female

**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)

**ROR**

<https://ror.org/054225q67>

**Funder(s)**

## Funder type

Research organisation

## Funder Name

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

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/03/2016	08/02/2019	Yes	No
<a href="#">Plain English results</a>			26/10/2022	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes