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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
21/01/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
10/03/2004	Completed	[X] Results
Last Edited	Condition category	Individual participant data
26/10/2022	Cancer	

#### 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

#### Contact name

**Prof Robert Leonard** 

#### Contact details

Director - South Wales Cancer Institute University of Wales Singleton Hospital Sketty Lane Sketty Swansea United Kingdom SA2 8AQ

# Additional identifiers

abc@email.com

#### **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

# Sponsor information

#### Organisation

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

#### Sponsor details

Cancer Research UK PO Box 123 London United Kingdom WC2A 3PX

#### 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

Plain English results

Output typeDetailsDate createdDate addedPeer reviewed?Results article01/03/201608/02/2019Yes

26/10/2022

No

Patient-facing?

No

Yes