

# An Open Randomised Trial of Zoladex versus CMF as Adjuvant Therapy in the Management of Node Positive Stage II Breast Cancer in Pre/Peri-Menopausal Women Aged 50 Years or Less

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/11/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr - -

### Contact details

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MRC Clinical Trials Unit  
222 Euston Road  
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United Kingdom  
NW1 2DA

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

### Study objectives

Not provided at time of registration

### 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)

Hospital

### Study type(s)

Treatment

## Participant information sheet

### Health condition(s) or problem(s) studied

Breast

### Interventions

Patients are randomised to one of two treatment arms:

1. Arm A: Zoladex, 3.6 mg given subcutaneously every 28 days for 2 years or until a treatment endpoint is reached.
2. Arm B: Chemotherapy with cyclophosphamide, methotrexate and 5-fluorouracil (CMF) repeated every 28 days for six cycles.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/1995

**Completion date**

31/12/1996

## Eligibility

**Key inclusion criteria**

1. Pre- or peri-menopausal
2. Node positive stage II breast cancer, at entry to study, consisting of:
  - 2.1. Histologically proven operable invasive breast cancer
  - 2.2. Pathologically involved lymph nodes
- c. No evidence of metastatic disease
3. No previous systemic therapy for breast cancer
4. Adequate hepatic, renal and haematological function
5. No bilateral oophorectomy or radiotherapy to the ovaries
6. No concurrent or previous malignancy, except squamous or basal cell carcinoma of the skin or carcinoma in situ of the cervix, adequately cone biopsied

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/1995

**Date of final enrolment**

31/12/1996

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**UKCCCR Register Co-ordinator**  
London  
United Kingdom  
NW1 2DA

## **Sponsor information**

**Organisation**  
AstraZeneca Clinical Research Group (UK)

**Sponsor details**  
10 Logie Mill  
Beaverbank Office Park  
Lovie Green Road  
Edinburgh  
United Kingdom  
EH7 4HG

**Sponsor type**  
Industry

**Website**  
<http://www.astrazeneca.co.uk>

**ROR**  
<https://ror.org/04r9x1a08>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
AstraZeneca Pharmaceuticals

## **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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	15/12/2002		Yes	No