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

Submission date	Recruitment status	Prospectively registered
19/08/2002 Registration date	No longer recruiting Overall study status	☐ Protocol
		Statistical analysis plan
19/08/2002	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
13/11/2012	Cancer	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

Additional identifiers

Protocol serial number ZEN2802

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre UKCCCR Register Co-ordinator

London United Kingdom NW1 2DA

Sponsor information

Organisation

AstraZeneca Clinical Research Group (UK)

ROR

https://ror.org/04r9x1a08

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca Pharmaceuticals

Results and Publications

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?
Results article	results	15/12/2002		Yes	No