ISRCTN15682734 https://doi.org/10.1186/ISRCTN15682734

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
19/08/2002

Recruitment status
No longer recruiting

Registration date
19/08/2002

Overall study status
Completed

Last Edited
13/11/2012

Condition category
Cancer

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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?
Results article	results	15/12/2002		Yes	No