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A Randomised Comparative Trial of Infusional ECF (Epirubicin, Cisplatin and 5-fluorouracil) versus Conventional AC (Adriamycin, Cyclophosphamide) as Primary (Neoadjuvant) Chemotherapy for Patients with at Least 3cm Diameter Early Breast Cancer

Submission date
19/08/2002

Recruitment status
No longer recruiting

Registration date
19/08/2002

Overall study status
Completed

Last Edited
02/09/2014

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
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Additional identifiers

Protocol serial number
ICR/TOPIC

Study information

Scientific Title

Acronym
TOPIC I

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 cancer

Interventions
1. Infusional ECF Regimen: Chemotherapy, ECF (epirubicin, cisplatin and 5-fluorouracil) treatment continuing 3 weekly for six courses
2. AC Regimen: Chemotherapy, AC (adriamycin, cyclophosphamide) treatment continuing 3 weekly for six courses

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Infusional ECF (Epirubicin, Cisplatin and 5-fluorouracil) versus Conventional AC

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/02/1999

Eligibility

Key inclusion criteria
1. Histologically or cytologically proven breast cancer
2. Aged <70 years
3. Potentially operable primary breast cancer more than 3 cm in diameter
4. Patients assessed as being competent to learn to look after Infumed or Graseby pump
5. World Health Organisation (WHO) performance status 0-1
6. No evidence of metastatic disease
7. Adequate haematological function
8. Glomerular filtration rate of at least 60 ml/min
9. No other serious uncontrolled medical condition
10. No other malignancy, except carcinoma in situ of the cervix or basal cell carcinoma of the skin

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
01/10/1993

Date of final enrolment
01/02/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London

United Kingdom
NW1 2DA

Sponsor information

Organisation
The Institute of Cancer Research (UK)

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Cancer Research (UK)

Alternative Name(s)
Institute of Cancer Research - CIHR, CIHR Institute of Cancer Research, L'Institut du cancer, L'Institut du cancer (IC), The Institute of Cancer Research (ICR), ICR, ICR - CIHR, IC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article	01/05/2004	Yes	No