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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 02/09/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/1993

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

Age group
Adult

Sex
Female

Target number of participants
426 patients from 18 centres, in active follow-up

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
England

United Kingdom

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

Sponsor information

Organisation
The Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Government

Website
http://www.icr.ac.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, Institut du cancer, ICR - CIHR, ICR, IC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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	01/05/2004		Yes	No