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	Recruitment status No longer recruiting	Prospectively registered		
19/08/2002		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/08/2002	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
02/09/2014	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

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

Kev 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