# 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	<ul><li>Prospectively registered</li></ul>
19/08/2002	No longer recruiting	☐ 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

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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

# 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