A Randomised Comparative Trial of Infusional ECF versus Conventional FEC as Adjuvant Chemotherapy in Patients with Poor Prognosis Breast Cancer

Submission date 19/08/2002	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 19/08/2002	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 03/12/2012	Condition category Cancer	Individual participant data

Plain English summary of protocol Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Prof I Smith

Contact details

Royal Marsden Hospital Downs Road Sutton Surrey United Kingdom SM2 5PT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ICR/TRAFIC

Study information

Scientific Title

Acronym TRAFIC

Study objectives

To compare the relapse-free survival and survival of adjuvant infusional ECF with conventional FEC chemotherapy in patients <50 with node-positive early breast cancer.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at registration time

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

 Infusional ECF Regimen: Chemotherapy, infusional ECF (epirubicin, cyclophosphamide, 5fluorouracil)
 FEC Regimen: Chemotherapy, conventional FEC (epirubicin, cyclophosphamide, 5-fluorouracil)

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Infusional ECF versus Conventional FEC

Primary outcome measure Not provided at time of registration

Secondary outcome measures Not provided at time of registration

Overall study start date 26/06/1995

Completion date

30/01/2002

Eligibility

Key inclusion criteria

- 1. Confirmed invasive carcinoma of the breast
- 2. Treatment to start within 3 months of surgery
- 3. World Health Organisation (WHO) performance status of zero or one
- 4. Patients assessed as being competent to learn to look after Infumed or Graseby pump
- 5. No evidence of metastatic disease (routine Chest X-RAY [CXR], biochemistry)
- 6. Adequate haematological function

7. A glomerular filtration rate of greater than or equal to 60mls/minute. This can be measured by using an EDTA clearance or 24 hour urinary creatinine clearance at the investigators discretion 8. No other serious uncontrolled medical condition

9. No other malignancy, except carcinoma in situ of the cervix of basal cell carcinoma of the skin

- 10. Histologically proven invasive breast cancer (excision specimen or Trucut biopsy)
- 11. Upper age limit 50 years
- 12. Histologically involved axillary nodes

13. Written informed consent

14. Other investigations, e.g. bone scan, liver ultrasound, are only required for symptoms and/or abnormal biochemistry

Participant type(s)

Patient

Age group

Adult

Sex Female

Target number of participants Added 14/07/08: 348 patients

Key exclusion criteria

1. Any patient with a medicinal or psychiatric condition that impairs their ability to cope physically or psychologically with this chemotherapy regimen, or to give informed consent

2. Uncontrolled angina pectoris, heart failure, clinically significant uncontrolled or cardiac arrhythmias

- 3. Any other serious uncontrolled medical condition
- 4. Any pregnant or lactating woman
- 5. Other malignancy (excluding carcinoma in situ of cervix)

Date of first enrolment 26/06/1995

Date of final enrolment 30/01/2002

Locations

Countries of recruitment England

United Kingdom

Study participating centre Royal Marsden Hospital Surrey United Kingdom SM2 5PT

Sponsor information

Organisation Institute of Cancer Research (ICR) (UK)

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

Sponsor type Research organisation

Website http://www.icr.ac.uk

ROR https://ror.org/043jzw605

Funder(s)

Funder type Research organisation

Funder Name Institute of Cancer Research (ICR) (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?
<u>Results article</u>	results	01/08/2010		Yes	No