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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

Registration date
19/08/2002

Overall study status
Completed

Last Edited
03/12/2012

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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast Cancer

Interventions
1. Infusional ECF Regimen: Chemotherapy, infusional ECF (epirubicin, cyclophosphamide, 5-fluorouracil)
2. 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(s)
Not provided at time of registration

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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

United Kingdom

England

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

Sponsor information

Organisation
Institute of Cancer Research (ICR) (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, 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 article	results	01/08/2010		Yes	No