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A multicentre phase II feasibility study of accelerated chemotherapy - sequential epirubicin followed by intravenous cyclophosphamide, methotrexate and fluorouracil - using pegfilgrastim for women with early stage breast cancer

Submission date	Recruitment status	[_] Prospectively registered
07/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/01/2020	Cancer	

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
BR2017

Study information

Scientific Title
A multicentre phase II feasibility study of accelerated chemotherapy - sequential epirubicin followed by intravenous cyclophosphamide, methotrexate and fluorouracil - using pegfilgrastim for women with early stage breast cancer

Acronym
NEAT-A

Study objectives
To explore the feasibility and toxicity of accelerated epirubicin, cyclophosphamide, methotrexate and fluorouracil (E-CMF) chemotherapy, using single doses of pegfilgrastim to reduce the interval between chemotherapy cycles, in a cohort of patients who would normally be treated with conventional E-CMF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by West Hertfordshire Local Research Ethics Committee on 01/11/2004, reference number: 04/Q0203/27

Primary study design
Interventional

Study design
Phase II non-randomised feasibility study

Study type(s)
Treatment

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

Interventions
Patients should be treated according to the following schedule:
D1 Epirubicin 100 mg/m^2 intravenous (i.v) administration
D2 Pegfilgrastim 6 mg single dose subcutaneous administration (s.c.)
Repeated every 14 days for four cycles.

Then either:
Classical i.v. CMF (option A)
D1 Cyclophosphamide 600 mg/m2 i.v.
Methotrexate 40 mg/m^2 i.v.
5-Fluorouracil 600 mg/m^2 i.v.

D8 Cyclophosphamide 600 mg/m^2 i.v.
Methotrexate 40 mg/m^2 i.v.
5-Fluorouracil 600 mg/m^2 i.v.

D9 Pegfilgrastim 6 mg single dose s.c.
Repeated every 21 days for 4 cycles. Folinic acid (15 mg orally (p.o.) six-hourly times six doses commencing 24 h post methotrexate) should be administered with all cycles of CMF

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Epirubicin, cyclophosphamide, methotrexate, fluorouracil, pegfilgrastim, folinic acid

Primary outcome(s)
Delivered dose intensity

Key secondary outcome(s)
Toxicity and safety

Completion date
01/07/2006

Eligibility

Key inclusion criteria
1. Histological diagnosis of invasive early breast cancer with complete excision following surgery
2. No evidence of metastatic disease
3. Clear indication for adjuvant chemotherapy based on clinical and histopathological features
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2
5. Clinically assessed as fit to undergo E-CMF chemotherapy at full dose
a. Haematological parameters within normal range for institution

b. Liver function tests (aspartate aminotransferase [AST] or alanine aminotransferase [ALT]) ≤1.5 upper limit of normal (ULN)
c. Adequate renal function with creatinine clearance >50 ml/min (calculated according to Cockcroft formula)
6. No previous chemotherapy or radiotherapy
7. Aged 18 years and over
8. Non-pregnant and non-lactating, with no intention of pregnancy during chemotherapy, and prepared to adopt adequate contraceptive measures if pre-menopausal and sexually active
9. Written informed consent obtained
10. No concomitant medical or psychiatric problems that might prevent completion of treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
44

Key exclusion criteria
1. Significant history of cardiac disease (prior myocardial infarction, angina, uncontrolled hypertension)
2. Any co-morbidity significantly adding to risks associated with cytotoxic chemotherapy for instance: severe chronic obstructive pulmonary disease, poorly controlled diabetes etc
3. Recent exposure to immunosuppressive drugs including oral corticosteroid
4. Inability to comply with protocol requirements

Date of first enrolment
04/03/2005

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cancer Research UK Clinical Trials Unit
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Industry

Funder Name
Educational grants from Amgen UK and Pfizer UK

Results and Publications

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?
Abstract results	results	20/06/2007	03/01/2020	No	No