

Prospective randomised comparison of granulocyte colony-stimulating factor (G-CSF) (filgrastim) secondary prophylaxis versus conservative management of chemotherapy-induced neutropenia to maintain dose intensity in chemotherapy for 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 ☐ Results
Last Edited 08/11/2012	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-trial-using-gcsf-to-try-to-reduce-the-risk-of-infection-in-people-having-chemotherapy-for-breast-cancer>

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

Protocol serial number

BR0101

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast

Interventions

Standard iv chemotherapy regimens as per local guidelines.

Patients entered into TACT or TANGO protocols, or other protocols of licensed chemotherapies which do not exclude G-CSF usage will be eligible for this protocol.

Patients in the SECRA trial will also be eligible. G-CSF to be dosed subcutaneously at 5 micrograms/kg from day 3 post chemotherapy until day 9 (7 days). For the purposes of dosing, the last day of chemotherapy administration will be day 1. In the case of Day 1/Day 8 regimens, G-CSF shall be dosed starting on day 10 for 7 days.

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. 18 years or older
2. Histologically confirmed invasive breast cancer
3. No concomitant malignancy
4. No prior chemotherapy (apart from the current regimen)
5. Previous neutropenic event on iv chemotherapy and considered of suitable risk and fitness to continue chemotherapy
6. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

03/10/2001

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom
NW1 2DA

Sponsor information

Organisation

Anglo Celtic Cooperative Oncology Group (UK)

Funder(s)

Funder type

Industry

Funder Name

Anglo Celtic Cooperative Oncology Group, Amgen (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration