ISRCTN89698860 https://doi.org/10.1186/ISRCTN89698860

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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
Not available in web format, please use the contact details below to request a patient information sheet

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 SECRAB 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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
03/10/2001

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
400

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
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Anglo Celtic Cooperative Oncology Group (UK)

Sponsor details
SCTN Central Office
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Sponsor type
Research organisation

Website
http://www.amgen.com

Funder(s)

Funder type
Industry

Funder Name
Anglo Celtic Cooperative Oncology Group, Amgen (UK)

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