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A randomised two-arm, prospective, multi-centre, open-label phase III trial comparing the activity and safety of a weekly versus a three-weekly paclitaxel treatment schedule in patients with advanced or metastatic breast cancer

Submission date 15/10/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 15/10/2002	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/10/2020	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-weekly-versus-3-weekly-paclitaxel-for-breast-cancer-that-has-spread

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
BR0201

Study information

Scientific Title
A randomised two-arm, prospective, multi-centre, open-label phase III trial comparing the activity and safety of a weekly versus a three-weekly paclitaxel treatment schedule in patients with advanced or metastatic breast cancer

Study objectives
Primary objectives:
1. To compare the antitumour efficacy of weekly versus three-weekly paclitaxel as determined by the time to disease progression
2. To study polymorphisms in the genes responsible for paclitaxel metabolism and link these to response rates and toxicity

Secondary objectives:
1. To compare the toxicity of weekly versus three-weekly paclitaxel
2. To compare the response rate of weekly versus three-weekly paclitaxel
3. To compare overall survival in patients receiving weekly versus three-weekly paclitaxel
4. To compare quality of life in patients receiving weekly versus three-weekly paclitaxel

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 cancer

Interventions
Arm 1: Paclitaxel (90 mg/m^2 intravenous [IV] over 1 hour on day 1 every week for 12 cycles)
Arm 2: Paclitaxel (175 mg/m^2 IV over 3 hours on day 1 every 3 weeks for 6 cycles)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Paclitaxel

Primary outcome(s)
1. Antitumour efficacy, as determined by the time to disease progression
2. Polymorphisms in the genes responsible for paclitaxel metabolism, response rates and toxicity

Key secondary outcome(s)
1. Toxicity
2. Response rate
3. Overall survival
4. Quality of life

Completion date
01/01/2006

Eligibility

Key inclusion criteria
1. Histologically proven breast cancer
2. Locally advanced or metastatic disease
3. Presence of measurable or evaluable lesions
4. Prior treatment with anthracyclines (either in the adjuvant setting or for metastatic disease) or contraindication to anthracyclines
5. Aged 18 years or greater
6. World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 2
7. Adequate haematological, renal and hepatic function
8. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
16/09/2002

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Newcastle Department of Oncology
Newcastle Upon Tyne
United Kingdom
NE4 6BE

Sponsor information

Organisation
Anglo Celtic Cooperative Oncology Group (UK)

Funder(s)

Funder type
Research organisation

Funder Name
Anglo Celtic Cooperative Oncology Group (UK) - supported by an educational grant from Bristol-Myers Squibb Pharmaceuticals Limited

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?
Plain English results				No	Yes