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

Submission date	Recruitment status	Prospectively registered
15/10/2002	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/10/2002	Completed	Results
Last Edited	Condition category	Individual participant data
07/10/2020	Cancer	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

Contact name

Dr M Verrill

Contact details

University of Newcastle Department of Oncology Newcastle General Hospital Westgate Road Newcastle Upon Tyne United Kingdom NE4 6BE +44 (0)191 219 4252 mark.verrill@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 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 measure

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

Secondary outcome measures

- 1. Toxicity
- 2. Response rate
- 3. Overall survival
- 4. Quality of life

Overall study start date

16/09/2002

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

600

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

England

United Kingdom

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)

Sponsor details

SCTN Central Office Information & Statistics Division

Trinity Park House South Trinity Road Edinburgh United Kingdom EH5 3SQ +44 (0)131 551 8363 joanna.dunlop@isd.csa.scot.nhs.uk

Sponsor type

Research organisation

Website

http://www.amgen.com

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

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

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Plain English resultsNoYes