

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/10/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/10/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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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

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Arm 1: Paclitaxel (90 mg/m² intravenous [IV] over 1 hour on day 1 every week for 12 cycles)

Arm 2: Paclitaxel (175 mg/m² 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

[Plain English results](#)

Details

Date created

Date added

Peer reviewed?

No

Patient-facing?

Yes