

Weekly versus three-weekly docetaxel in women with breast cancer

Submission date 25/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/01/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Weekly doses of the drug docetaxel have occasionally been used to treat patients with breast cancer. The aim of this study is to compare the effect of weekly versus the standard three-weekly docetaxel treatment on patients' quality of life.

Who can participate?

Women aged 18 -70 with breast cancer.

What does the study involve?

After 4 cycles of doxorubicin and cyclophosphamide treatment, participants are randomly allocated to receive either 12 cycles of weekly docetaxel or 4 cycles of three-weekly docetaxel.

What are the possible benefits and risks of participating?

Weekly docetaxel may cause fewer side effects and therefore improve patients' quality of life. The common side effect of chemotherapy is febrile neutropenia (fever).

Where is the study run from?

Lincoln County Hospital (UK)

When is the study starting and how long is it expected to run for?

July 2000 to November 2002

Who is funding the study?

Sanofi Aventis (UK); Royal Thai Army, Bangkok (Thailand); Prince of Songkla University, Songkla (Thailand)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

Prof Oleg Eremin

Contact details

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Additional identifiers**Protocol serial number**

Trial 206(n) protocol 1.0

Study information**Scientific Title**

A randomised controlled study of weekly versus three weekly docetaxel in women with breast cancer

Study objectives

The hypothesis was that weekly docetaxel versus three weekly regime resulted in comparable quality of life without compromising treatment efficacy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nottinghamshire Research Ethics Committee, 05/04/2000, ref: 206(n)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary breast cancer

Interventions

Arm A: 12 cycles of weekly docetaxel intravenously (IV) 100 mg/m² for 12 weeks treatment
Arm B: 4 cycles of three-weekly docetaxel IV 100 mg/m² for 4 weeks treatment

Follow-up for both arms was 75.5 months.

Intervention Type

Drug

Phase

Phase II/III

Drug/device/biological/vaccine name(s)

Docetaxel

Primary outcome(s)

Quality of life 3 weeks after completion of chemotherapy

Key secondary outcome(s)

1. Clinical and pathological responses at 12 weeks
2. Disease free survival and overall survival at 5 years

Completion date

01/11/2002

Eligibility**Key inclusion criteria**

1. Women aged 18 - 70 years
2. Unilateral/bilateral large (greater than or equal to 3 cm) or locally advanced primary breast cancer (T3, T4, TxN2), no distant metastases
3. World Health Organization (WHO) performance status of less than 2
4. Adequate cardiac, haematological, renal, and hepatic function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

Female

Key exclusion criteria

1. Pregnant
2. Previous malignancy (except curatively treated carcinoma in situ of the cervix or basal cell carcinoma of skin)
3. Previous cytotoxic, endocrine, or radiotherapy
4. Active infection
5. Contraindications to corticosteroid administration
6. Pre-existing neurotoxicity (greater than grade 2) as defined by the National Cancer Institute Common Toxicity Criteria (NCI-CTC)
7. Significant cognitive impairment or dementia
8. Inability to complete quality of life (QoL) questionnaires or provide informed consent

Date of first enrolment

01/07/2000

Date of final enrolment

01/11/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Lincoln County Hospital

Lincoln

United Kingdom

LN2 5QY

Sponsor information

Organisation

United Lincolnshire Hospitals NHS Trust (UK)

ROR

<https://ror.org/0377kyv52>

Funder(s)

Funder type

Industry

Funder Name

Sanofi-Aventis Pharmaceuticals (UK)

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?
Results article	results	18/05/2011		Yes	No