

# Weekly versus three-weekly docetaxel in women with breast cancer

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

Prof. Oleg Eremin  
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## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Oleg Eremin

**Contact details**

Research & Development  
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LN2 5QY

**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**

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

**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**

Primary breast cancer

**Interventions**

Arm A: 12 cycles of weekly docetaxel intravenously (IV) 100 mg/m<sup>2</sup> for 12 weeks treatment

Arm B: 4 cycles of three-weekly docetaxel IV 100 mg/m<sup>2</sup> 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 measure**

Quality of life 3 weeks after completion of chemotherapy

**Secondary outcome measures**

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

**Overall study start date**

01/07/2000

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

70 Years

**Sex**

Female

**Target number of participants**

41 in 2 trial arms (82 in total)

**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**

England

United Kingdom

**Study participating centre**

Lincoln County Hospital

Lincoln

United Kingdom

LN2 5QY

# Sponsor information

## Organisation

United Lincolnshire Hospitals NHS Trust (UK)

## Sponsor details

Greetwell Road  
Lincoln  
England  
United Kingdom  
LN2 4AX

## Sponsor type

Hospital/treatment centre

## Website

<http://www.ulh.nhs.uk/>

## ROR

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

# Funder(s)

## Funder type

Industry

## Funder Name

Sanofi-Aventis Pharmaceuticals (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	18/05/2011		Yes	No