

# Randomised phase II study comparing capecitabine with oral cyclophosphamide and capecitabine in patients with advanced breast cancer

<b>Submission date</b> 29/08/2003	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/10/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/12/2008	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Vernon Harvey

### Contact details

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Auckland  
New Zealand  
1003

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

### Acronym

CycloX II

### Study objectives

A phase II study comparing two chemotherapy treatments for advanced breast cancer - capecitabine and capecitabine with cyclophosphamide. Both drugs being used are taken by mouth, and are both already used to treat breast cancer, but they are not usually used together.

### 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

### Health condition(s) or problem(s) studied

Advanced breast cancer

### Interventions

100 mg/m<sup>2</sup>/day cyclophosphamide days 1 - 14 plus capecitabine 1331 mg/m<sup>2</sup>/day days 1 - 28, every 28 days versus capecitabine 1331 mg/m<sup>2</sup>/day days 1-28, every 28 days alone.

### Intervention Type

Drug

### Phase

Phase II

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

Capecitabine, cyclophosphamide

**Primary outcome measure**

Added as of 16/12/2008:

1. Toxicity assessed throughout treatment, assessed 8-weekly during the treatment period
2. Best tumour response, assessed 8-weekly during the treatment period

**Secondary outcome measures**

Added as of 16/12/2008:

1. Survival measures, assessed at completion of the study
2. Symptom response, assessed throughout treatment

**Overall study start date**

01/01/2004

**Completion date**

02/03/2007

## Eligibility

**Key inclusion criteria**

1. Women with advanced breast cancer (distant metastasis, or T4, N2 or N3, or local recurrence following mastectomy)
2. Measurable disease (Response Evaluation Criteria in Solid Tumors [RECIST])
3. Treatment with palliative intent
4. At least one prior course of chemotherapy for advanced disease

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

82 (as of 02/03/2007)

**Key exclusion criteria**

Added as of 16/12/2008:

1. Male
2. Less than six months since last dose of adjuvant chemotherapy
3. More than one prior regimen for advanced disease
4. Pregnant or breast feeding
5. Concurrent anti-cancer therapy
6. Other malignancy within 5 years except adequately treated basal cell or squamous cell carcinoma of the skin or in-situ carcinoma of the cervix

**Date of first enrolment**

01/01/2004

**Date of final enrolment**

02/03/2007

## **Locations**

**Countries of recruitment**

New Zealand

**Study participating centre****Department of Oncology**

Auckland

New Zealand

1003

## **Sponsor information**

**Organisation**

Cancer Trials New Zealand (CTNZ) (New Zealand)

**Sponsor details**

Faculty of Medical & Health Sciences

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**Sponsor type**

Research organisation

**Website**

<http://www.ctnz.auckland.ac.nz/>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Roche Products Ltd (New Zealand)

**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