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

Submission date 29/08/2003	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/10/2003	**Overall study status** Completed	
Last Edited 16/12/2008	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CTNZ 01-03; ACTRN12605000377639

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^2/day cyclophosphamide days 1 - 14 plus capecitabine 1331 mg/m^2/day days 1 - 28, every 28 days versus capecitabine 1331 mg/m^2/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 thoughout 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 thank 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
University of Auckland
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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