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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

Registration date
28/10/2003

Overall study status
Completed

Last Edited
16/12/2008

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
Added as of 16/12/2008:
1. Survival measures, assessed at completion of the study
2. Symptom response, assessed throughout treatment

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

Funder(s)

Funder type
Industry

Funder Name
Roche Products Ltd (New Zealand)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration