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Pilot Phase III immunotherapy study in early breast cancer patients using oxidized mannan-MUC1

Submission date	Recruitment status	[_] Prospectively registered
17/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/05/2008	Cancer	

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
EOF-27581

Study information

Scientific Title

Acronym
IFCM9

Study objectives
To evaluate patients with early/minimal residual disease of breast cancer after injection with oxidized mannan-MUC1.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Greek ethics committee approval 26 September 1997

Study design
A randomized double-blinded pilot study.

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Early breast cancer (Stage II)

Interventions
Injection with oxidized mannan-MUC1 versus placebo. This trial tests whether this method of injecting and the stage of the patient receiving vaccine is beneficial in patients against recurrence of breast cancer.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Oxidized mannan-MUC1

Primary outcome(s)
After more than 5.5 years from last patient start (8 years from first patient treatment), the recurrence rate in patients receiving the placebo was 4/15 (the expected rate of recurrence in Stage II breast cancer); those receiving immunotherapy had no recurrences (0/16) a statistically significant result ($p = 0.0292$). Of the patients receiving oxidized mannan MUC1, 9/13 had measurable antibodies to MUC1 and 4/10 had MUC1 specific T cell responses; none of the placebo treated patients showed an immune response to MUC1.

Key secondary outcome(s))
The results suggest that in early breast cancer, MUC1 immunotherapy is beneficial, and that a larger Phase III study should be undertaken.

Completion date
18/06/2003

Eligibility

Key inclusion criteria
1. Postmenopausal women (no menstrual period for >12 months)
2. Histological proven adenocarcinoma of the breast treated primarily by modified radical or partial mastectomy and axillary dissection followed by radiation of the residual breast
3. No more than 4 ipsilateral lymph nodes with metastases, not extending into the surrounding tissue and surgical margin free of disease
4. Tumor tissue with positive estrogen receptor
5. Tamoxifen 20 mg daily commencing within three months of breast surgery and to continue for 5 years
6. Adequate bone marrow function (white blood cells >4.0 x 10^9 per litre, haemogoblin >100 g per litre, platelets >100 x 10^9 per litre)
7. Adequate liver function (billirubin <60 mmol/litre i.e. < x 3 upper limit of normal)
8. Adequate renal function (creatinine <140 mmol/litre)
9. Life expectancy >12 weeks
10. Eastern Cooperative Oncology Group (ECOG) status between 0-2 (in bed <50% of daytime)
11. Written informed consent by the patient

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Known metastatic breast cancer
2. Radiotherapy, chemotherapy, immunotherapy or investigation therapy within the last 4 weeks
3. Previous splenectomy or radiotherapy to spleen
4. Coexisting or previous other malignancies except in situ carcinoma of the cervix or basal cell carcinoma of the skin
5. Active uncontrolled infection
6. Psychiatric, addictive or any disorder which compromises ability to give truly informed consent for participation in this study or comply with the requirements of the study
7. Concurrent systematic corticosteroid treatment
8. Autoimmune disease i.e. rheumatoid arthritis, systematic lupus erythematosus, except autoimmune thyroiditis

Date of first enrolment
13/12/1997

Date of final enrolment
18/06/2003

Locations

Countries of recruitment
Australia

Greece

Study participating centre
The Austin Research Institute
Heidelberg
Australia
3084

Sponsor information

Organisation
Prolipsis Medical Center (Greece)

Funder(s)

Funder type
Research organisation

Funder Name
The Austin Research Institute, Heidelberg VIC Australia and Prolipsis Medical Center, Athens Greece.

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:	01/04/2006	Yes	No