

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

<b>Submission date</b> 17/03/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/03/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/05/2008	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Prevention

## Participant information sheet

## 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 measure**

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.

**Secondary outcome measures**

The results suggest that in early breast cancer, MUC1 immunotherapy is beneficial, and that a larger Phase III study should be undertaken.

**Overall study start date**

13/12/1997

**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  $>4.0 \times 10^9$  per litre, haemoglobin  $>100$  g per litre, platelets  $>100 \times 10^9$  per litre)
7. Adequate liver function (billirubin  $<60$  mmol/litre i.e.  $< \times 3$  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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

**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)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Funder(s)****Funder type**

Research organisation

**Funder Name**

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

**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:	01/04/2006		Yes	No