

# A multicentre phase III randomised controlled study of Theratope vaccine for metastatic breast cancer

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 10/03/2015	<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

---

### Contact details

UKCCCR Register Co-ordinator  
MRC Clinical Trials Unit  
222 Euston Road  
London  
United Kingdom  
NW1 2DA

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

C136

# Study information

## Scientific Title

A multicentre phase III randomised controlled study of Theratope vaccine for metastatic breast cancer

## Study objectives

Not provided at time of registration

## 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

Breast cancer

## Interventions

1. Theratope s/c injections 100 mg with detox at weeks 0, 2, 5 and 9
2. Control injection Keyhole limpet haemocyanin 100 mg with detox at weeks 0, 2, 5 and 9

## Intervention Type

Drug

## Phase

Phase III

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

Theratope

## Primary outcome measure

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2000

**Completion date**

31/12/2005

## **Eligibility**

**Key inclusion criteria**

1. Must have received 4-8 cycles or 12-24 weeks duration of first-line chemotherapy for metastatic disease
2. Has either no evidence of disease or non-progressive disease following first-line chemotherapy or stable disease

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Female

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2000

**Date of final enrolment**

31/12/2005

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**MRC Clinical Trials Unit**  
London  
United Kingdom  
NW1 2DA

## **Sponsor information**

### **Organisation**

UK Co-ordinating Committee for Cancer Research (UKCCCR)

### **Sponsor details**

MRC Clinical Trials Unit  
222 Euston Road  
London  
United Kingdom  
NW1 2DA

### **Sponsor type**

Government

### **ROR**

<https://ror.org/054225q67>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

Cancer organisations

## **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