

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

Submission date 19/08/2002	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 10/03/2015	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

UK Co-ordinating Committee for Cancer Research (UKCCCR)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Cancer organisations

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration