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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 10/03/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
- - -

Contact details
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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 heamocyanin 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 of 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
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United Kingdom
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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