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Double-blind, placebo-controlled randomised trial of alpha-tocopherol and oxpentifylline in patients with radiation fibrosis

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 25/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00022204

Protocol serial number
SP2313/0201

Study information

Scientific Title
Double-blind, placebo-controlled randomised trial of alpha-tocopherol and oxpentifylline in patients with radiation fibrosis

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
Double-blind placebo-controlled randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
1. DL-Alpha Tocopheryl Acetate 500 mg (or placebo) po BD for 6 months
2. Oxpentifylline 400 mg (or placebo) po BD for 6 months

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Alpha-tocopherol, oxpentifylline

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2001

Eligibility

Key inclusion criteria

1. Past history of early breast cancer (T1-3 N0 M0)
2. No axillary surgery or lower axillary sampling only
3. Radiotherapy to the breast/chest wall plus axilla and or stem cell factor (SCF)
4. A minimum of 5 years post-radiotherapy
5. No evidence of cancer recurrence
6. Disabilities due to previous radiotherapy
7. Ability to attend RMT Sutton for assessments
8. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1996

Date of final enrolment
31/12/2001

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2004	25/01/2019	Yes	No