

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

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/01/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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

**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?
<a href="#">Results article</a>	results	01/11/2004	25/01/2019	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes