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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
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00022204

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1996

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

Age group
Adult

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
01/01/1996

Date of final enrolment
31/12/2001

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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

Study outputs

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