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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW12DA

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