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Pentoxifylline and vitamin E treatment for prevention of radiation induced side effects in women with breast cancer

Submission date	Recruitment status	[_] Prospectively registered
11/10/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/10/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/07/2009	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Ptx-5

Study information

Scientific Title

Acronym
Ptx-5

Study objectives
Primary objective:
To investigate if pentoxifylline and vitamin E prevent radiation induced side effects measured as impaired shoulder mobility in women treated for breast cancer with radiotherapy to the axilla and breast.

Secondary objective:
To investigate if pentoxifylline and vitamin E prevent radiation-induced side effects measured as lymphoedema, and Late Effects Normal Tissue task force Subjective, Objective, Management, and Analytic (LENT-SOMA) breast score in women treated for breast cancer with radiotherapy to the axilla and breast.

Tertiary objective:
To investigate if pentoxifylline and vitamin E influence development of new Radiation-Induced Fibrosis (RIF) areas as measured with an impedance method and to investigate if pentoxifylline influence the plasma levels of Transforming Growth Factor-beta1 (TGF-beta1) in women treated for breast cancer with radiotherapy to the breast and axilla.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Lund University Ethics Committee on the 8th December 2003 (ref: LU758-03).

Study design
The trial is randomised, single centre, placebo controlled, double-blinded, with a parallel study design. Randomisation is stratified for previous cytostatic treatment

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients will be included in the study one month after termination of radiotherapy. At that time all other active cancer treatment will be finished, except for anti-hormone treatment with tamoxifen, letrozol, anastrozole and exemestane that are allowed as concomittant medication in this study.

During the first visit the patients will be assessed for eligibility and given a screening number. They will be informed about the study and the purpose of it. After giving their informed consent

the subjects will undergo a physical examination, and their medical history will be obtained. The inclusion and exclusion criteria will be checked and then the subject will be randomised to a treatment group and given a patient number.

There are two treatment groups in the study. Both groups have the same number of patients:
Group A: treated with pentoxifylline and vitamin E
Group B: treated with placebo and vitamin E

Pentoxifylline/placebo will be escalated to 400 mg three times daily. The vitamin E dose will be 100 mg three times daily. The patients will be treated for 12 months.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pentoxifylline, vitamin E

Primary outcome(s)
Shoulder mobility is assessed by a goniometer; axillary movement will be analysed first time when all 80 patients have finished the first year of medication.

Key secondary outcome(s))
1. Lymphoedema, assessed by measurement of water displacement
2. LENT-SOMA breast score, assessed every 3 months during the year of medication, twice in year 2 and yearly for 3 years up to 5 years
3. Impedance measurement of RIF areas
4. Plasma TGF-beta1 levels, analysed as a separate part of the study when patients have been included for 1 year

Secondary endpoint will be analysed (blinded) after one year of medication. All patients will be followed for 5 years and the final analysis will be done when all patients have been followed for 5 years.

Completion date
10/05/2012

Eligibility

Key inclusion criteria
1. Women (no age limit) with breast cancer
2. Treated with axillary dissection, mastectomy or segmental resection of the breast, and radiotherapy to the breast and axilla
3. All active cancer treatment is terminated, except for anti-hormone treatment with tamoxifen, letrozol, anastrozole, and exemestane
4. Able to understand the nature of the trial and give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Known sensitivity to pentoxifylline or vitamin E
2. Disorders related to muscles or joints
3. Corticosteroid treatment during radiotherapy treatment

Date of first enrolment
13/05/2004

Date of final enrolment
10/05/2012

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Oncology
Lund
Sweden
SE 221 85

Sponsor information

Organisation
Lund University Hospital (Sweden)

ROR
https://ror.org/012a77v79

Funder(s)

Funder type

Research organisation

Funder Name
Swedish Cancer Society (Cancerfonden) (Sweden) (ref: 4981-B05-02XBC)

Alternative Name(s)
Swedish Cancer Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

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	01/09/2009		Yes	No