

Effect of biphosphonates on teleangiectasia in irradiated breast cancer patients

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To determine the effects of biphosphonates on radiation induced microvascular damage in the skin of breast cancer patients by comparing skin biopsies taken prior to and 4 months after treatment with a biphosphonate.

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON36371

Source

ToetsingOnline

Brief title

The biphosphonate modulation of telangiectasia study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Skin vascular abnormalities

Synonym

biphosphonates and telangiectasia in irradiated breast cancer patients.

Research involving

Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut

Source(s) of monetary or material Support: KWF

Intervention

Keyword: biphosphonate, breastcancer, radiotherapy, telangiectasia

Outcome measures

Primary outcome

To determine the effects of biphosphonates on radiation induced microvascular damage by comparison of biopsy samples of skin prior to and 4 months after treatment with a biphosphonate.

Secondary outcome

To determine the effects of biphosphonates on radiation induced micro-lymphovascular damage by comparison of biopsy samples of skin prior to and after treatment with a biphosphonate.

Study description

Background summary

About half of all cancer patients who have survived up to 20 years following diagnosis receive radiotherapy sometimes as being one of the main components of multimodality cancer treatment with also chemotherapy and surgery. Vascular injury is the major cause of late radiation morbidity developing slowly and progressively over many years and currently there is no preventative treatment. Our hypothesis is that biphosphonate inhibit the release of bone marrow derived mononuclear cells, and that this will have a beneficial effect on the development of pathogenic microvasculature.

Study objective

To determine the effects of biphosphonates on radiation induced microvascular damage in the skin of breast cancer patients by comparing skin biopsies taken prior to and 4 months after treatment with a biphosphonate.

Study design

The study is as follows: Three different groups of patients with breast cancer

can be entered in this trial. In the past all groups underwent radiotherapy for breast cancer and now will be treated with biphosphonate. Two times two skin biopsies will be taken, before and after four months of treatment with a biphosphonate. This is to compare whether biphosphonates have an effect on inhibition of vascular damage in the irradiated skin.

Study burden and risks

Two biopsies will be taken during the regular hospital visit. It will take 10 minutes extra time. The skin round the biopsy area will be anaesthetized and a 4 mm diameter, 1 mm deep punch biopsy will be taken. A bleeding is possible but very rare and will be solved by using a plaster.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

radiotherapie on breast > 6 months ago
will receive biphosphonate
age >=<18 years

Exclusion criteria

breast radiotherapy < 6 months ago
use of anti-coagulants

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-02-2011

Enrollment: 40

Type: Anticipated

Ethics review

Approved WMO

Date: 26-05-2011

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35067.031.10