# 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.

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| **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 survivied 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 receice biphosphonate
age ><=18 years

### Exclusion criteria

breast radiotherapy < 6 months ago
use of anti-coagulants

## Study design

### Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2011 |
| Enrollment: | 40 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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|---|---|
| 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 |