Potential role of vitamin D treatment in breast cancer.

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To assess impact of high doses vitamin D on tumour histology in breast cancer patients.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28013

Bron
Nationaal Trial Register

Verkorte titel
POVIDIB

Aandoening

Vitamin D, breast cancer, apoptosis, proliferation

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: Fund Coronis, Researchfund of department of gynaecologists Enschede

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To study the influence of vitamin D on immunohistochemical marker Ki 67 (proliferation marker) in breast cancer. This marker will be defined in the biopsy specimen and in the tumour resection specimen. The mean difference between these two marker values will be

examined between the intervention and the control group.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Data obtained in in vivo and in vitro as well as in epidemiological studies suggest important and beneficial effects of vitamin D on histological parameters in breast cancer.

Objective:

To assess impact of high doses vitamin D on tumour histology in breast cancer patients.

Study design:

Prospective randomized controlled trial (double blinded).

Study population:

Patients with primary operable breast cancer.

Intervention:

1. Vitamin D supplementation, 40.000 IU/day in the intervention group and placebo in the control group, both 55 patients each. Supplementation starts after breast cancer diagnosis is communicated with the patient and will be continued until surgery is performed. Maximum duration of treatment is 5 weeks. If patients are treated less than 3 weeks they will be excluded from analysis;

2. Blood samples (vitamin D, calcium and creatinine assessment) will be taken at time of diagnosis and every 14 days until day of surgery and at day of surgery.

Primary Objective:

1. To study the influence of vitamin D on immunohistochemical marker Ki 67 (proliferation marker) in breast cancer. This marker will be defined in the biopsy specimen and in the tumour resection specimen. The mean difference between these two marker values will be examined between the intervention and the control group.

Secondary Objective(s):

1. To study the influence of vitamin D on immunohistochemical markers in biopsy specimen and tumour resection specimen in breast cancer. These markers will be defined in the biopsy specimen and in the tumour resection specimen. Immunohistochemical markers to be studied are:

A. Caspase 3 (apoptosis marker);

B. Vitamin D receptors (responsiveness marker);

C. HER 2Neu-, estrogen- and progesterone-receptor status (tumormarkers).

2. To study changes in serum calcium and vitamin D levels between day of diagnosis and day of surgery;

3. Correlation of initial (=before treatment with vitamin D) serum vitamin D levels with clinicopathological parameters of breast cancer (tumour size, nodal status, grade, estrogen and progesterone receptor status, HER2 status);

4. Reporting any eventual adverse effects.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

1. Daily intake of Vitamin D (orally) (burden);

2. Extra blood samples at day of diagnosis, after that with a two-week interval and at day of surgery (vitamin D, calcium and creatinine assessment) (burden);

3. The potential and biological plausible positive effects on primary tumour and circulating tumour cells (benefit).

Doel van het onderzoek

To assess impact of high doses vitamin D on tumour histology in breast cancer patients.

Onderzoeksopzet

Immunohistochemical markers from biopsy compared to surgical tissue, from 3 weeks to 8 weeks.

Each lab result at day of diagnosis, every 14 days and at day of surgery, from 3 weeks to 8 weeks.

Onderzoeksproduct en/of interventie

Oral administration of colecalciferol 40,000 IU/day, the duration of this therapy will be about 3-8 weeks (time frame between diagnosis of breast cancer and definitive surgery).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Primary operable invasive breast cancer;

2. Women;

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Primary:

1. Inability to comply with a study protocol (e.g. abuse of alcohol, drugs, psychotic states);

2. (Previously) clinically detected nefrolithiasis (on diagnostic imaging techniques);

3. (Previously) clinically detected cholelithiasis (on diagnostic imaging techniques);

4. History of sarcoidosis;

5. History of recurrent urolithiasis;

6. Already taking Vitamin D (colecalciferol) supplement >400 IU/day;

7. Calcium-lowering therapy within 2 weeks before study entry;

8. Previously documented impaired renal function;

9. Previous or concomitant anti-cancer therapy (chemotherapy, radiotherapy);

10. Other treatment with an investigational drug. (current participation in any other therapeutic clinical trial).

Secondary:

1. If patients are treated with vitamin D or placebo less than 3 weeks they are excluded from analysis.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34378
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2537
NTR-old	NTR2655
CCMO	NL33552.044.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34378

Resultaten

Samenvatting resultaten
N/A