Potential role of vitamin D treatment in breast cancer.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28013

Source
Nationaal Trial Register

Brief title
POVIDIB

Health condition

Vitamin D, breast cancer, apoptosis, proliferation

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Fund Coronis, Researchfund of department of gynaecologists Enschede

Intervention

Outcome measures

Primary outcome

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 outcome

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.

Study description

Background summary

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).

Study objective

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

Study design

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.

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

1. Primary operable invasive breast cancer;

2. Women;

3. Informed consent.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2011
Enrollment:	110
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 34378
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A