The effect of Vitamin D3 to prevent postoperative relapse of Crohn*s Disease: a placebo-controlled randomized trial (DETECT)

Published: 06-09-2013
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This trial will provide definitive answers with regard to the anti-inflammatory effects of Vitamin D in Crohn*s disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON44853

Source
ToetsingOnline

Brief title
DETECT

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders
- Gastrointestinal therapeutic procedures

Synonym
crohn's disease, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,BROAD Medical Research Program

Intervention

Keyword: Crohn's Disease, recurrence, surgery, Vitamin D

Outcome measures

Primary outcome

The proportion of patients with clinically significant endoscopic recurrence

(grades i2b, i3 and i4) at 6 months after preventive treatment with vitamin D

(or placebo) in the setting of postoperative Crohn*s Disease will be studied.

The endoscopic appearance at 6 months postoperatively has reliably been

predictive of the ensuing clinical course of the disease.

Secondary outcome

The proportion of patients in clinical remission. Moreover, the influence of

vitamin D treatment will be analysed based on patients* NOD2/CARD15 genotype.

Lastly quality of life will be investigated.

Study description

Background summary

The majority of patients with Crohn*s disease need to undergo surgical bowel resection. Postoperative recurrence of the disease is virtually inevitable and continues to be one of the most challenging therapeutic problems in IBD. Medical treatments to prevent recurrence have had limited effect. Anti-TNF agents appear promising but are hampered by immunogenicity, side effects and high cost.
Vitamin D has recently received a lot of scientific attention and was found to have strong anti-inflammatory and antifibrotic effects in gut and liver

inflammation. Many CD patients appear to have deficiency in Vitamin D. A controlled trial to prevent relapse of CD in medical (not surgical) remission suggested a preventive effect for Vitamin D but marginally missed its endpoint because of lack of power.
The ultimate proof of the anti-inflammatory effect of Vitamin D in Crohn*s disease can best be studied in the prevention of postoperative recurrence.

Study objective

This trial will provide definitive answers with regard to the anti-inflammatory effects of Vitamin D in Crohn*s disease.

Study design

Prospective placebo-controlled trial with Vitamin D drops 25.000 IU/week versus placebo for 6 months in patients who have undergone ileocolonic resection for Crohn*s disease with a primary endpoint of endoscopic recurrence as defined by Rutgeerts* criteria.
Immediately following the surgery eligible patients will be randomized (1:1) to postoperative treatment with Vitamin D 25.000 IU/week or placebo.

Intervention

The study subjects will receive either 25.000 IU vitamin D3 weekly or placebo, for 26 weeks.

Study burden and risks

Excessive levels of 25(OH)D may result in hypervitaminosis D, which results in hypercalcemia. We consider the risk of hypervitaminosis D and hypercalcemia in this trial extremely low based on the doses of Vitamin D we will use. Nonetheless, Vitamin D and calcium levels will be monitored throughout the trial by an independent physician not involved in the care of the patients. The month 6 ileocolonoscopy is currently standard of care and carries the well-known risks of colonoscopy.

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

- Age * 18 years, either male or female
- Established CD
- First or second ileocolonic resection with ileocolonic anastomosis and removal of all tissue macroscopically affected by CD according to the surgeon
- Able to give written informed consent
- Normal levels of serum calcium at inclusion, corrected for albumin
- Being able to resume oral intake within 2 weeks after surgery

Exclusion criteria

- Patients in whom not all visible CD has been resected
- Active fistulizing perianal disease (requiring anti TNF treatment)
- Extensive small bowel resection
- Third, fourth or later ileocolonic resection
- Patients undergoing ileocoecal resection in the Lir!c Trial (NTR 1150, http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=1150)
- A history of primary hyperparathyroidism
- A history of osteoporosis for which calcium and Vitamin D treatment are mandatory
- A history of another granulomatous diseases (sarcoïdosis, tuberculosis)
- Pregnant or breastfeeding (at index date) female patients

- Patients undergoing other resections than ileocolonic resections
- Patients who prefer to use open-label vitamin D preparations

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2014
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	D-Cura
Generic name:	D-Cura
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Invita D3
Generic name:	Invita D3
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	06-09-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2013-002838-20-NL
CCMO	NL45391.018.13