Effect of CAlcium on intestinal PErmeability and Diarrhea in Ulcerative Colitis

Published: 18-02-2009
Last updated: 06-05-2024

PRIMARY• To investigate whether calcium supplementation, in addition to standard induction therapy, decreases intestinal permeability (Chroom EDTA) in patients with active ulcerative colitis.• To observe whether calcium supplementation, in addition...

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

Summary

ID

NL-OMON32623

Source
ToetsingOnline

Brief title
CAPEDUC

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic intestinal inflammation, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Top Institute Food and Nutrition
Source(s) of monetary or material Support: Top Institute Food and Nutrition

Intervention

Keyword: calcium, diarrhea, intestinal permeability, ulcerative colitis

Outcome measures

Primary outcome

-intestinal permeability

-diarrhea

Secondary outcome

-percentage patients with a clinical response and clinical remission at 2-4-6-9

and 12 weeks

-percentage patients needing oral steroids

-inflammatory activity as measured by inflammation markers in blood and feces

(fecal blood, calprotectin, mucins, and pancreatitis associated protein (PAP))

Study description

Background summary

We have shown in several controlled studies that dietary calcium improves gut health. This is based on several mechanisms. Besides preventing intestinal bacterial translocation, calcium has cytoprotective effects as shown in several studies in the field of colon carcinogenesis. By precipitating irritating bile acids and fatty acids, supplemental calcium reduces cytotoxicity of the fecal stream, which reinforces mucosal integrity. Additionally, calcium can protect against diarrhea. Moreover, we have shown that dietary calcium reduces intestinal permeability. An increased permeability is one of the major characteristics of ulcerative colitis. Beneficial effects of calcium have been shown in rats as well as humans. For example, calcium was protective in a rat model of chronic intestinal inflammation. Although there are several similarities between animals and humans, the question whether calcium is beneficial for patients with ulcerative colitis can only be answered by doing scientific research with patients.

Study objective

PRIMARY
• To investigate whether calcium supplementation, in addition to standard induction therapy, decreases intestinal permeability (Chroom EDTA) in patients with active ulcerative colitis.
• To observe whether calcium supplementation, in addition to standard induction therapy, diminishes diarrhea (fecal dry weight) in patients with active ulcerative colitis.
SECONDARY
• To evaluate whether calcium supplementation, in addition to standard induction therapy, increases the percentage patients with a clinical response and clinical remission at 2-4-6-9 and 12 weeks.
• To determine whether calcium supplementation, in addition to standard induction therapy, decreases the percentage patients needing oral steroids.
• To determine whether calcium supplementation, in addition to standard induction therapy, diminishes inflammatory activity as measured by inflammation markers in blood and feces (fecal blood, calprotectin, mucins, and pancreatitis associated protein (PAP)).

Study design

Randomized double-blind placebo controlled multicenter nutritional intervention study

Intervention

Subjects will receive tablets with or without 500 mg calcium twice daily for 12 weeks.

Study burden and risks

Patients can maintain their habitual diet, except for some dairy products. At the start of the study, patient need to fill in a short food frequency questionnaire. Every measurement (week 0, 2, 4, 6, 9 and 12) patients need to take a CrEDTA-capsule, and feces and urine are collected for the next 24h. Blood will be taken at 3 visits (week 0, 6 and 12), when the patient will also visit their physician. At these visit patients undergo a short physical examination. Disease activity will be determined using a short scoring index at every measurement (week 0, 2, 4, 6, 9 and 12). The visit, blood drawing included, is part of standard therapy.

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

•Patients between 18 and 70 years (inclusive) of age
•A diagnosis of UC, confirmed by conventional endoscopic and histological criteria
•Relapse documented by a SCCAI score boven 2.5
•Exacerbation can be first manifestation of disease or an exacerbation of known disease
•Patients must have tested negative for stool cultures including Clostridium difficile
•Patients who are capable of understanding the purpose and risks of the study and who provided a signed and dated written informed consent

Exclusion criteria

-UC requiring immediate surgical, or radiological interventions, including massive hemorrhage, perforation and sepsis, suppurative complications (intra-abdominal or peri-anal abscesses) or toxic colon
-investigator judgment that the subject is likely to require a colectomy within 12 weeks of baseline
-history of large bowel surgery or presence of a stoma
-presence or history of a fistula

-patients with serious infections
-significant organ dysfunction (serum creatinine >140 µmol/l, ALT/AST exceeding 3 times the ULN, platelets <100, white blood cells <2.5*109 cell/l)
-some concomitant medication (see protocol)
-pregnant women or nursing mothers
-patients with kidney stones or other illness possibly leading to hypercalceamia or hypercalciuria
-calcium supplement use and unwillingness to stop supplement intake 3 days prior to screening and during the intervention period
-unwillingness to partly restrict dairy intake during the intervention

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2008
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL24265.042.08
Other	volgt nog