

# Multivitamin and mineral supplement for infection in patients with IBD

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24663

### Source

Nationaal Trial Register

### Brief title

Vitamin study

### Health condition

Inflammatory Bowel Disease

## Sponsors and support

**Primary sponsor:** New Care

**Source(s) of monetary or material Support:** N/A

## Intervention

## Outcome measures

### Primary outcome

The difference in incidence of infection between the 2 intervention groups.

### Secondary outcome

Infections per organ, postponement or discontinuation with the IBD therapy, hospitalization

and exacerbation of IBD

## Study description

### Background summary

**Rationale:** Patients with inflammatory bowel disease treated with immunomodulators or biological therapy, and in particular anti-tumor necrosis factor (anti-TNF) are at increased risk of infections. Malnutrition and vitamin or mineral deficiencies are common among patients with inflammatory bowel disease. The results of various studies have indicate that vitamin deficiencies increase the risk for infections.

**Objective:** To evaluate the efficacy of an over the counter multivitamin and mineral supplement, compared with an identically in appearance placebo on the incidence of infections in patients with inflammatory bowel disease with a high risk for infection.

**Study design:** Single-center, randomized, double-blinded, placebo-controlled, clinical trial to evaluate the efficacy of multivitamin and mineral supplement versus placebo on the incidence of infections in patients with Crohn's disease or ulcerative colitis. Patients will be stratified for disease and then randomly assigned in a 1:1 ratio to receive multivitamin and mineral supplement or placebo.

### Study objective

Supplementation with an over the counter multivitamin and mineral supplement (New Care Multi®) for 24 weeks in the winter and spring can prevent infections in patients with inflammatory bowel disease in remission with immunomodulators or biological therapy.

### Study design

Week 0, 12 and 24

### Intervention

Group A will receive an over the counter multivitamin and mineral supplement (New Care Multi®), once daily for the period of 24 weeks.

Group B will be randomized to receive the placebo, identical in appearance, for the same period of follow up.

## Contacts

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## Eligibility criteria

### Inclusion criteria

- Patients between the ages of 18 and 75 years old.
- Patients diagnosed with Crohn's disease or Ulcerative Colitis.
- Patients using immunomodulators (azathiopurine, mercaptopurine and thioguanine) and/ or anti-TNF therapy (infliximab, adalimumab, golimumab).

### Exclusion criteria

Patients with active inflammation. Disease has to be in remission defined as CRP  $\leq$  10mg/l, leucocytes between 4.0-10.0  $10^9/l$  and feces calprotectin levels of  $\leq$  100 $\mu$ g/g.

Patients whose laboratory values not within the reference ranges ; chemistry panel, renal function, hepatic function, vitamin B12 and albumin, including but not limited to hemoglobin, iron ( $> 8\mu$ mol/L) and folic acid levels ( $> 9$ nmol/L).

Patients who used vitamin supplements, antibiotics or Non-Steroidal Anti- Inflammatory Drugs (NSAIDs) in the 4 weeks prior to the screening visit, or are planning to do so during the study period.

Patients who are pregnant, lactating or planning pregnancy while enrolled in the study. (The investigational product contains caffeine which can be harmful for the unborn and newborn child.)

Patients who are unsuitable for inclusion in the study in the opinion of the investigator for any reason that may compromise the subject's safety or confound data interpretation.

## Study design

## Design

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

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2020
Enrollment:	320
Type:	Actual

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	08-04-2021
Application type:	First submission

## 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

NTR-new

Other

### ID

NL9410

METC Brabant : P1939

## Study results