Multivitamin and mineral supplement for infection in patients with IBD

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24663

Source
NTR

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 ≤ 10mg/l, leucocytes between 4.0-10.0 10E9/l and feces calprotectin levels of ≤ 100µg/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 (> 8µmol/L) and folic acid levels (> 9nmol/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	ID
NTR-new	NL9410
Other	METC Brabant : P1939

Study results