Multivitamin and mineral supplement for infection in patients with IBD

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24663

Bron
Nationaal Trial Register

Verkorte titel
Vitamin study

Aandoening

Inflammatory Bowel Disease

Ondersteuning

Primaire sponsor: New Care
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Week 0, 12 and 24

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	320
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9410
Ander register	METC Brabant : P1939

Resultaten