A randomized, double-blinded placebo controlled trial to evaluate the efficacy of a multivitamin and mineral supplement to prevent infections in patients with inflammatory bowel disease.

Published: 09-01-2020
Last updated: 19-07-2024

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.

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

Summary

ID

NL-OMON55309

Source
ToetsingOnline

Brief title
Multivitamin and mineral supplement for infection in patients with IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic bowel inflammation, Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Geen vergoeding

Intervention

Keyword: IBD, infection, mineral, multivitamin

Outcome measures

Primary outcome

The primary endpoint of this study is the difference in incidence of infections measured by preformatted questionnaire and clinical data between the multivitamin and mineral and placebo group.

Secondary outcome

The secondary endpoints of the study are the differences in quality of live indicated by the Inflammatory Bowel Disease Questionnaire, in fatigue as measured by the Chalder Fatigue Questionnaire, stool frequency and -consistency measured by the Bristol Stool Scale and disease activity measured by standard clinical and laboratory assessments.

Study description

Background summary

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.

Study 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.

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.

Study burden and risks

Participants will be asked to fill out the above mentioned questionnaires as indicated by the table of assessments at the start of the study and at each regular outpatient clinic visit at 12 and 24 weeks. Furthermore, daily practice laboratory assessments will be collected during the study, as being part of the regular outpatient clinic visits of the patients. Multivitamin and minerals supplement side effects, if they occur, tend to be very mild.

Contacts

Public
Sint Elisabeth Ziekenhuis

Hilvarenbeekseweg 60
Tilburg 5022GC
NL
Scientific
Sint Elisabeth Ziekenhuis

Hilvarenbeekseweg 60
Tilburg 5022GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients between the ages of 18 and 75 years old;
* Patients diagnosed with Crohn*s disease or Ulcerative Colitis;
* Patients using immunomodulators and/ or biologic therapy.

Exclusion criteria

- patients with active inflammation;
- patients who has undergone surgical resection or are expected to require during the stuy
- patients wo are pregnant or planning pregnancy.

Study design

Design

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):	01-09-2020
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO Date:	09-01-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-02-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-09-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-04-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL71054.028.19