Physical fitness and activity in Inflammatory Bowel Disease patients

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON34164

Source
ToetsingOnline

Brief title
Physical fitness and activity in IBD patients

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease / Ulcerative Colitis, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Physical activity, Physical fitness

Outcome measures

Primary outcome

1. To what extent patients with IBD have a reduced level of daily physical

activity compared to healthy population?

2. To what extend the level of fitness is decreased in IBD patients compared to

healthy population?

3. Is the level of daily physical activity related to the severity of fatigue ?

4. Is fitness related to the severity of fatigue in patients with IBD?

Secondary outcome

1. What is the relationship between fitness and physical activity daily?

2. Is fitness and / or daily physical activity related to the quality of life

in patients with IBD?

Study description

Background summary

Inflammatory bowel disease (IBD) are chronic intestinal inflammation. IBD is subdivided into two subcategories: Ulcerative colitis (UC) and Crohn's disease (CD). Annual 1500 IBD patients visit the outpatient clinic of the Erasmus MC. The average frequency of visits is twice a year, but this frequency increases to once a month in about 60% of patients. Reasons for this increased frequency of visits are: active disease, side effect of medication and fatigue. It is known that at least 41% of patients without active disease suffer from extreme fatigue.
Fatigue could result in a defensive and ineffective use of medical care and resources and thus to more frequent visits, more tests and regularly changing treatment. It is also possible that patients because of their complaints have less physical activity and poor fitness and so a vicious circle which

complaints may continue to deteriorate.
An inactive lifestyle and low fitness may also have a negative impact on health-related quality of life and is associated with an increased risk of getting heart disease, diabetes and cancer. Several studies have shown a positive effect of physical activity to the quality of life and mental wellbeing.
Nevertheless, IBD patients there is no treatment to promote physical activity in daily life and improving fitness. Reason for this, probably lies in the fact that there is currently little knowledge about physical activity, fitness and the relationship with fatigue in this patient group.
Therefore there is a demand for evaluation studies of interventions in IBD patients with extreme fatigue and impaired quality of life. Knowledge of determinants of fatigue in IBD is necessary to develop interventions for successful rehabilitation of patients with IBD.

Study objective

The study aims to determine whether fitness and daily physical activity determine fatigue in patients with IBD. Therefore we will examine whether there is a relationship between fitness, daily physical activity and fatigue in these patients. It will also examine whether there is a relationship between fitness, physical activity and quality of life in patients with IBD.
This exploratory pilot study will possibly direct the development of a rehabilitation program for patients with IBD fatigue. Upon completion of this investigation there will be launched an intervention study where the effects of a rehabilitation program will be investigated.

Study design

prospective pilot study

Study burden and risks

No risks are expected associated with participation. Furthermore, no benefits are expected with participation.

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

Included will be patients, age: 18-65 year, have to be in remission according to the investigator, based on accepted clinical parameters and medical records (CDAI <150, CAI <10 and CRP < 10 or at endoscopy).

Exclusion criteria

Excluded will be patients who are pregnant or breastfeading; surgery 3 months prior or intended after this study; short bowel syndrome, cancer, and underlying psychiatric disorders, other gastrointestinal disorder (other than IBD), contraindication for maximal physical test.

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	29-10-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL33396.078.10