Cerebral Magnetic Resonance Imaging in active Crohn*s Disease patients with fatigue

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38079

Source
ToetsingOnline

Brief title
Cerebral MRI in Crohn*s Disease patients

Condition

- Other condition
- Gastrointestinal inflammatory conditions

Synonym
cerebral metabolism, fatique

Health condition

cerebrale metabole veranderingen

Research involving
Human

Sponsors and support

Primary sponsor: MDL
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cerebral, Crohn□s Disease, Fatigue, Magnetic Resonance Imaging

Outcome measures

Primary outcome

the presence of:

Elevated levels of choline

cerebral structural changes

Secondary outcome

NA

Study description

Background summary

Inflammatory bowel diseases (IBD), Crohn*s disease (CD) and ulcerative colitis (UC), are chronic inflammatory diseases characterized by inflammation of (a part of) the gastrointestinal tract with a relapsing and remitting course. IBD patients with active disease as well as in remission, frequently complain of fatigue. This often has consequences for patients* work and social lives and the importance of fatigue in chronic disease has been increasingly recognized. A hospital-based and population-based study showed prevalence rates of fatigue in Dutch IBD patients in remission of 41% and 12,5% respectively, resulting in a lowered Health Related Quality of Life (HRQoL).(1,2) Furthermore, Romberg-Camps et al. (2) showed that CD patients suffered significantly more from fatigue and scored lower on the quality of life questionnaires compared to UC patients.

Despite the high prevalence of fatigue, it remains poorly understood. From studies with patients with the chronic fatigue syndrome (CFS), it has been shown that there is an association between elevated levels of choline (a marker of cell membrane turnover) and fatigue.(3,4)

Reumatoïd arthritis (RA) is a chronic inflammatory autoimmune disease. Apart from joint complaints, patients frequently complain of neuropsychiatric symptoms (mood disorders, sleep disturbances) and fatigue.(5,6) In 2009, (protocolnumber #p232/99) researchers from the LUMC departments of Rheumatology, Radiology and Neurology have demonstrated an association between inflammation in reumatoïd arthritis (RA) patients and metabolic changes in the brain, using Magnetic Resonance Spectroscopy (1H-MRS).(7) Elevated levels of choline were present in patients with active RA. Furthermore, the ratios of choline to creatine were positively correlated with the erythrocyte sedimentation rate (ESR) and with the disease activity in RA patients (DAS28). The clinical consequences, like nonspecific symptoms such as fatigue and the pathophysiological processes of elevated choline levels are still unknown and therefore, further research is necessary.

Study objective

The aim of this pilot study is to assess whether the cerebral metabolic changes in RA patients, are also present in CD patients with active disease and fatigue. The influence of chronic inflammation on cerebral metabolism in CD patients will be determined by 1H-MRS on a 3T MRI. 1H-MRS results of CD patients will be compared to the 1H-MRS results of a group of healthy controls. Furthermore, cerebral changes will be examined by MRI and these changes will be related to clinical symptoms (e.g. fatigue), disease activity and neuropsychological examination.
If such changes can be detected, it would pave the way for a more comprehensive study into the nature of the observed changes, and it would provide essential ammunition for a full grant application.

2. OBJECTIVE
1) To investigate the influence of chronic inflammation on the cerebral metabolism in CD patients

2) To detect cerebral structural changes in CD patients

3) To correlate the MRI changes to clinical characteristics, disease activity and neuropsychological investigation.

Study design

The study is initiated by the department of Gastroenterology & Hepatology, the department of Radiology, the department of Neurology and Neuropsychology the department of Rheumatology of the Leiden University Medical Center, Leiden, the Netherlands.

The study is a single center pilot case-control study

Study burden and risks

The patient has to sypply a blood and feces sample, lie still in the MRI scanner for 1 hour and undergo neuropsychological investigation.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women age18-40 years
Crohn*s Disease patients with active bowel disease (Harvey Bradshaw Index, HBI>4) and fatigue with a numerical rating scale (NRS) of 6 or more (on an 11-point NRS)
Endoscopic or histological proven Crohn*s disease at least 3 months before inclusion
Healthy persons, without cerebral or central nervous system disease or other chronic

inflammation in the body

Exclusion criteria

Comorbidity for fatigue: e.g. anemia (Hb< 7,0 mmol/L or ferritine < 10 ug/L)
Routine MRI-contraindications (e.g. instable metal implants, pacemaker/ICD, vascular clips)
TNF-alpha treatment, methotrexate within 12 weeks before inclusion
Pregnancy

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:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-10-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	02-05-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL37249.058.11