Tryptophan enriched diet to improve affective and cognitive functions in patients with multiple sclerosis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON34520

Source
ToetsingOnline

Brief title
Effects of tryptophan enriched diet in MS patients

Condition

- Demyelinating disorders

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: Stichting MS Research

Intervention

Keyword: cognition, mood, multiple sclerosis, tryptophan

Outcome measures

Primary outcome

The Profile of Mood States (POMS) and the Positive and Negative Affect Scale (PANAS) are used prior, 2h and 4 h after treatment to determine changes in mood. Changes in plasma TRP levels and the TRP/*LNAA ratio will be determined over several hours after intake.

Secondary outcome

Attention processes (Trail Making Test, Affective Go/NoGo and Stroop test) and memory functions (affective memory test) are tested 3 h after intake.

Study description

Background summary

Multiple sclerosis is a chronic neurologic disease characterized by physiological and/or immunological abnormalities that can diminish synthesis of serotonin leading to metabolic deregulation or less efficient neurotransmission. Based on the regulatory function of serotonin on mood, it is very likely that a deficiency in serotonergic metabolism induced by MS-related factors might at least partly underlie mood disturbances which could secondary induce cognitive deficits and affect quality of life in MS patients.
Serotonin synthesis in brain is regulated by its precursor tryptophan (TRP). Because tryptophan is an essential amino acid, modifying the availability of tryptophan through dietary intake, can directly influence central serotonin metabolism and consequently affective and cognitive processes. The hypothesis is that an acute intake of a TRP enriched meal attenuates neuropsychological dysfunctions in MS patients, especially when having mood disturbances.

Study objective

The purpose of this study is to test the acute effects of a TRP enriched meal in a dose-dependent manner in MS patients. The results of MS patients without

mood disturbances (control group) will be compared to MS patients with mood disturbances (study group) in order to investigate whether the latter are more sensitive to or have more benefit of this nutritional approach. As a result, we can select the most optimal nutritional formulation for MS patients with respect to neuropsychological functions. Based on the outcomes of these studies, we can investigate the relationship between serotonergic system, mental processes and MS in more detail. When finding proof-of-principle, a larger group of patients will be used to identify specific markers that can predict the therapeutic effects of a TRP-enriched diet on neuropsychological functions and that can improve early recognition of the symptoms

Study design

The project comprises a phase II, double-blind placebo-controlled crossed-over acute nutritional intervention study in which a whey protein meal with additional TRP is given to MS patient with and without mood disturbances. To examine the acute effects of this meal in a dose-dependent manner, each subject will undergo four identical experimental test days, at least one week between two test days. Each subject will receive a control condition (without TRP) and three doses of TRP. This project is designed to give specific indications in order to select the most optimal nutritional formulation for MS patients with respect to neuropsychological functions. The combination of measuring plasma TRP levels, assessment of mood and cognitive functions (i.e. attention and memory) after nutritional intervention will enable quantification of the main endpoints of this study.

Intervention

We will test the acute effects of a whey protein meal where TRP levels can easily be modified in a dose-dependent manner. On each experimental test session, the subject is given a liquid whey protein meal with or without an additional amount of TRP by bolus feeding (400 ml). Each subject will receive a session with a whey protein mixture without TRP (placebo) and three sessions with whey protein mixture added with different amount of TRP.

Study burden and risks

The potential benefits of this nutritional intervention will be substantial to the patients in terms of an acute increase in mood state and cognitive functionality. The burden associated with participation is limited to five visits to the hospital. During each visit, neuropsychological assessments (tests and questionnaires) are used to evaluate effects on affective and cognitive processes. A catheter will be place before the start of every session to reduce inconvenience of frequently collecting blood samples (5 times/ session). In addition, this nutritional intervention is essential risk-free, although might result in temporary side effects such as nausea, drowsiness or

fatigue. These effects might be induced by the amount of liquid (400 ml) that has to be consumed as quickly as possible. However, the risks are outweighed by the benefit of the information that will be gained from the study. Increasing TRP availability by nutritional intervention has to date not been used in MS patients. By investigating the acute effects of this TRP-enriched meal in a dose-dependent manner, we are able to select the most optimal nutritional formulation for MS patients with respect to neuropsychological functions. Additionally, such an approach holds promise for guiding the identification of subgroups of patients most likely to benefit from TRP enriched meals.

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

Diagnosis of multiple sclerosis

Exclusion criteria

1) Subjects with clinically significant disease other than MS
2) Subjects who have used anti-depressive medication with 6 months before the beginning of the study.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL32316.096.10