The effect of natalizumab treatment on functional adaptation in multiple sclerosis (MS)

Published: 31-05-2010
Last updated: 01-05-2024

The main objective of the study is to investigate whether the strong clinical effects of natalizumab in RRMS can be explained by enhanced functional adaptation mechanisms of the brain and whether enhanced functional reorganisation is sustained over...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40114

Source
ToetsingOnline

Brief title
Natalizumab and functional adaptation

Condition

- Autoimmune disorders
- Demyelinating disorders

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Biogen-Idec B.V. is de subsidiërende partij

van deze investigator-initiated studie.

Intervention

Keyword: functional adaptation, multiple sclerosis (MS), natalizumab, resting-state fMRI

Outcome measures

Primary outcome

Functional connectivity changes, as measured by fMRI, will be used as an outcome measure for studying the effect of pharmacotherapeutical treatment.

Secondary outcome

Progression of disability will measured through change in Extended Disability Status Schale (EDSS) and Multiple Sclerosis Functional Composite (MSFC). Cognitive decline as measured by change in Brief Repeatable Battery - Neuropsychological tests (BRB-N) scores.

Subproject fatigue

Almost all patients with MS experience symptoms of (severe) fatigue. This can be either cognitive fatigue or physical fatigue. Therefore we also want to answer the following research question: Is physical fatigue related to cognitive fatigue? And what is the role of coping style with regard to fatigue (as measured with the different questionnaires).

For the two additional time points, we also would like to address the following research question: Does natalizumab enhance structural damage over time?

Study description

Background summary

Cognitive impairment in MS has not been as extensively investigated as physical disability in MS, although cognitive impairment is reported in 40% to 65% of MS patients at both the earlier and later stages of the disease. Patients with MS that are cognitively impaired experience several problems in daily living. Natalizumab has an anti-inflammatory effect and significantly reduces relapse rate, disability progression and lesion development in Relapsing Remitting Multiple Sclerosis (RRMS) patients. In response to CNS (Central Nervous System) damage - including inflammation - the brain has to functionally adapt. We hypothesize that the anti-inflammatory effect of natalizumab will amplify the effect on functional adaptation. This enhanced functional adaptation will have a positive outcome on disability, progression and cognitive decline.

Study objective

The main objective of the study is to investigate whether the strong clinical effects of natalizumab in RRMS can be explained by enhanced functional adaptation mechanisms of the brain and whether enhanced functional reorganisation is sustained over time. Does natalizumab affect functional connectivity as measured by resting-state functional Magnetic Resonance Imaging (fMRI)? Does enhanced functional adaptation, induced by natalizumab treatment, affect physical disability and cognitive decline?

Study design

The study is a prospective, single-centre, observational, longitudinal patient-control study assessing the effect of natalizumab on functional adaptation in RRMS patients.

Study burden and risks

For the two additional timepoints:

For the natalizumab patient group, at 24 months and 48 months visits the fMRI, MTR and BRB-N are extra in addition to their annual medical monitoring. The SDM group has no frequent medical monitoring, consequently, similar to the first visits, MRI, fMRI, MTR BRB-N, EDSS and MSFC will be conducted at the 24 and 48 month visits.

The risk of f(MRI) is negligible, especially after screening for risk-factors

prior to the (f)MRI.

Contacts

Public
Vrije Universiteit Medisch Centrum

Van Der Boechorststraat 7
Amsterdam 1007 MB
NL
Scientific
Vrije Universiteit Medisch Centrum

Van Der Boechorststraat 7
Amsterdam 1007 MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 18-65
RRMS
Meet safety criteria for MRI
Group 1: starting or recently started natalizumab
Group 2: using standard treatment

Exclusion criteria

MS other than RRMS
Presence or history of psychiatric disease
Presence or history of neurologic disease
Presence or history of alcohol or drug abuse

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-06-2010
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tysabri
Generic name:	natalizumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	31-05-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2010-020765-24-NL
CCMO	NL32274.029.10

Study results

Results posted: 28-02-2020

First publication
01-01-1900