

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	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 be measured through change in Extended Disability Status Scale (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

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### Scientific

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## 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**

EudraCT

CCMO

**ID**

EUCTR2010-020765-24-NL

NL32274.029.10

## Study results

Results posted:

28-02-2020

**First publication**

01-01-1900