

# Effects of fingolimod on advanced brain measures and clinical measures in multiple sclerosis

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24446

### Source

NTR

### Health condition

multiple sclerosis, functional magnetic resonance imaging, cognition, functional brain adaptation

multiple sclerose, functionele MRI, cognitie, functionele brein adaptatie

## Sponsors and support

**Primary sponsor:** VU University Medical Center

**Source(s) of monetary or material Support:** Novartis

## Intervention

## Outcome measures

### Primary outcome

- Improved neuropsychological test performance
- Changed functional MRI/connectivity

- Improved cognitive well-being

### **Secondary outcome**

NA

## **Study description**

### **Study objective**

We expect that the disproportionally strong clinical effects of fingolimod in relapsing remitting multiple sclerosis can be explained by enhanced functional adaptation mechanisms of the brain and that enhanced functional adaptation will be sustained over time

### **Study design**

baseline, 6 months and 18 months

### **Intervention**

(functional) magnetic resonance imaging and neuropsychological testing

## **Contacts**

### **Public**

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### **Scientific**

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## Eligibility criteria

### Inclusion criteria

- Subjects should be between 18 and 65 years of age
- Subjects should meet the safety criteria to undergo MRI examination
- Patients should be diagnosed with RRMS

### Exclusion criteria

- Presence or history of psychiatric or neurological disease (for patients: neurological disease other than MS)
- Presence or history of drug abuse
- For patients: relapse or steroid treatment less than four weeks prior to examination
- Insufficient visual acuity and motor skills to perform the fMRI task

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2014
Enrollment:	70

Type: Anticipated

## Ethics review

Not applicable

Application type: Not applicable

## 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
NTR-new	NL4522
NTR-old	NTR4657
Other	Novartis : CFTY720DNL02T

## Study results