A prospective, open-label, non-interventional phase IV study to investigate the COgnitive status, MOod, fatigue and quality of life in relapsing remitting multiple sclerosis patients treated with teriflunomide (Aubagio®) in Daily routine Observational Setting.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25460

Source
NTR

Brief title
COMODO trial

Health condition

Patients with Relapsing Remittent Multiple Sclerosis

Sponsors and support

Source(s) of monetary or material Support: Sanofi Genzyme
Gooimeer 10, 1411 DD Naarden,The Netherlands

Intervention

Outcome measures

Primary outcome

Change in cognitive status from baseline to 36 months, measured by the Brief Repeatable Battery – Neuropsychological (BRB-N)

Secondary outcome

• change in cognitive status measured by the BRB-N from baseline to month 12 and 24

• change in mood measured by the HADS from baseline to month 12 – 24 – 36

• change in fatigue measured by the MFIS from baseline to month 12 – 24 – 36

• change in QoL measured by MSIS-29 from baseline to month 12 – 24 – 36

• Pairwise Correlation within the time points baseline – M12 – M24 – M36 between:

o Cognitive status and mood

o Cognitive status and fatigue

o Cognitive status and Quality of Life

• (serious) Adverse events

Study description

Study objective

To characterize the effect of Aubagio on the Cognitive status, measured by the Brief Repeatable Battery – neuropsychological (BRB-N battery) in RRMS patients

Study design

Estimated enrolment duration: 18 months

Estimated date for first patient in (FPI): Q3 2016

Estimated Last Patient In (LPI): Q1 2018

Estimated Last Patient Last Visit (LPLV): Q1 2021

Database lock: Q2 2021

Publication: Q3 2021

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

• Patients with RRMS according the McDonald criteria 2010 and approved SmPC of Aubagio

• Treatment naïve RRMS patients or currently being treated with Aubagio for no more than 2 month or previously treated (with other first-line DMDs) with a wash-out period according to the respective SmPC before starting Aubagio. (verification has occurred prior to study enrollment)

• EDSS score ≤ 4

• Patients who are willing and able to sign written consent

Exclusion criteria

Severe disability and/or any neurological or severe psychiatric disorder, history of alcohol/ drugs abuse, history of traumatic brain injury with residual symptoms which might interfere with cognitive performance and other questionnaire outcomes

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2016
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-07-2016
Application type:	First submission

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	NL5804
NTR-old	NTR5959
Other	: TERIFL07828

Study results