A 4-month, open-label, multi-center study to explore tolerability and safety and health outcomes of FTY720 in patients with relapsing forms of multiple sclerosis (CFTY720D2316)

Published: 07-06-2010
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Primary: Safety and tolerability of fingolimod 0,5 mg in a broader population of MS patients.Explorerend: incidence of macular edema, bradyarrythmia, Patient-Reported Outcomes Indices for Multiple Sclerosis (PRIMuS) and Short Form Health Survey*12 (...

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

Summary

ID

NL-OMON36707

Source
ToetsingOnline

Brief title
CFTY720D2316

Condition

- Neurological disorders NEC

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma BV.

Intervention

Keyword: FTY720, relapsing multiple sclerosis, safety, tolerability

Outcome measures

Primary outcome

Side effects. Special attention for bradyarrythmia (AV conduction

disturbances), ophthalmic and skin abnormalities.

Secondary outcome

incidence of macular edema, bradyarrythmia, Patient-Reported Outcomes Indices

for Multiple Sclerosis (PRIMuS) en Short Form Health Survey*12 (SF-12),

Treatment Satisfaction Questionnaire for Medication (TSQM-9).

Study description

Background summary

Fingolimod (FTY720) is a new oral treatment for multiple sclerosis (MS). The application for a market authorization has been submitted to the authorities. It is an immunosupperssant. Fingolimod decreases the number of activated T-cells in blood and in the CNS by binding to the sphingosin-1-phosphate receptor-1 (S1P1) on circulating lymfocytes. This binding results in a reversible sequestration of T-cells, thus *trapping* autoagressive T-cells in peripheral lymoid tissues. Therefore they are not able to migrate to areas of inflammation in the CNS.
Fingolimod reduces the number of MS relapses and improves the MRI findings and inflammatory markers.
The current study has been designed to further explore safety and tolerability of fingolimod in a broader population of MS patients compared to previous phase III studies.

Study objective

Primary: Safety and tolerability of fingolimod 0,5 mg in a broader population of MS patients.
Explorerend: incidence of macular edema, bradyarrythmia, Patient-Reported Outcomes Indices for Multiple Sclerosis (PRIMuS) and Short Form Health Survey* 12 (SF-12), Treatment Satisfaction Questionnaire for Medication (TSQM-9).

Study design

Open, non-comparative phase IIIB safety study with fingolimod 0,5 mg daily during 4 months. 1st dose of study medication will be given in the clinic or at home, depending on the findings of the screening 24 h Holter monitoring. Hotler monitoring during at least 6 h post intake of the 1st dose.
Approx. 2400 patients.
Patiënten may be eligible for a follow-up study after completion of this study.

Intervention

Treatment with fingolimod.

Study burden and risks

Risks: Adverse effects of study medication.
Burden: 5-6 visits in 30 weeks. During all visits vital signs, blood tests (10-15 ml per visits, 75 ml in total; during screening HIV and hepatitis B-C) and pregnancy test (if relevant). 5x physical examination, 2x ECG, 2x Holtermonitoring (24 and 6 h), 2x ophthalmalogical examination (incl. OCT measurement), 1x skin examination. 2x (visits 1 or 2 and 5) completion of Patient-Reported Outcomes Indices for Multiple Sclerosis (PRIMuS) and Short Form Health Survey*12 (SF-12), Treatment Satisfaction Questionnaire for Medication (TSQM-9).
Advice for monthly self-inspection of the skin.

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

* Male or female subjects aged 18-65 years.
* Subjects with relapsing forms of MS.
* EDSS score 0-6.5.

Exclusion criteria

* Patients with a history of chronic disease of the immune system other than MS.
* Uncontrolled diabetes mellitus (HbA1c > 7%).
* Diagnosis of macular edema during Screening Phase.
* Patients with active systemic bacterial, viral or fungal infections. Positive HIV antibody, Hepatitis B surface antigen or Hepatitis C antibody tests.
* Negative for varicella-zoster virus IgG antibodies at Screening.
* Have received any live or live attenuated vaccines within 1 month prior to baseline.
* Corticosteroids or ACTH within 1 month prior to baseline.
* Immunosuppressive medications within 3 months prior to baseline.
* Immunoglobulins and/or monoclonal antibodies within 3 months prior to baseline.
* Cladribine, cyclophosphamide or mitoxantrone at any time.
* Patients with impaired cardiovascular condition and/or findings in the screening ambulatory 24-hour ECG-recording (see protocol for details).
* Pulmonary fibrosis.
* Abnormal liver conditions (see protocol for details).
* Pregnancy, lactation, inadequate contraception.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2010
Enrollment:	57
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Gilenia
Generic name:	fingolimod

Ethics review

Approved WMO Date:	07-06-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-08-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-08-2010
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-09-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-10-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-01-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2011
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
Other	clinicaltrials.gov; registratienummer nog niet bekend
EudraCT	EUCTR2010-019029-32-NL
CCMO	NL32141.029.10