Open-label, single-arm extension study to the double-blind, randomized, multicenter, placebo-controlled, parallel-group study comparing the efficacy and safety of 0.5 mg FTY720 administered orally once daily versus placebo in patients with primary progressive multiple sclerosis (CFTY720D2306E1)

Published: 03-01-2013
Last updated: 24-04-2024

Primary: Safety and tolerability of fingolimod 0,5 mg.Secundairy: Efficacy and quality of life.

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

Summary

ID

NL-OMON39777

Source
ToetsingOnline

Brief title
CFTY720D2306E1

Condition

- Autoimmune disorders
- Demyelinating disorders

Synonym

multiple sclerosis; MS

Research involving
Human

Sponsors and support

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

Intervention

Keyword: fingolimod, multiple sclerosis, primary progressive

Outcome measures

Primary outcome

Adverse events.

Secondary outcome

MRI, symptoms, adverse events, 9HPT, 25TWT, patient reported outcomes.

Study description

Background summary

Fingolimod (FTY720) is a new oral treatment for multiple sclerosis (MS). It has recently been registered for the indication relapsing-remitting MS. The development for the indication primary progressive MS (PPMS) is now ongoing. Fingolimod 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 is a follow-up study of the double blind placebo-controlled study CFTY720D2306 in patients with PPMS in order to collect additional long-term safety data and to enable patients to continue fingolimod treatment until the drug has obtained the registration for this indication. New patients are not eligible.

Study objective

Primary: Safety and tolerability of fingolimod 0,5 mg.
Secundairy: Efficacy and quality of life.

Study design

Open, non-comparative phase IIIB safety study for patients coming from the ongoing study CFTY720D2306, with fingolimod 0,5 mg daily until the drug has obtained the registration for the indication PPMS and reimbursement status in the Netherlands. 1st dose of study medication will be given in the clinic. Monitoring during at least 6 h post intake of the 1st dose.
Approx. 700 patients.

Intervention

Treatment with fingolimod.

Study burden and risks

Risks: Adverse effects of study medication.
Burden: Visits day 1, month 1, thereafter every 3 months and after the 2nd year every 6 months until registration and reimbursement in NL. Duration approx. 3h (at first dose observation period of 6 h). First visit = last visit of preceding study.
During all visits blood tests (approx. 10 ml, during screening incl. hepatitis A-B-C-E, HIV) and urine testing once.
Physical examination and dermatological examination every year.
Ophthalmological examination (incl. OCT measurement) start, month 3.
ECG baseline and day 1.
25 ft walking test, 9 hole peg test and EDSS every 6 months thereafter.
MRI brain yearly.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients initially randomized to fingolimod 1.25 mg or placebo as part of the first study cohort of CFTY720D2306, who have completed at least 3 years on study drug treatment.
* Patients initially randomized to fingolimod 0.5 mg or placebo as part of the second study cohort of CFTY720D2306 who have continued on study drug treatment until such time as the last ongoing patient enrolled in the study has reached 3 years in study.
* Still on study medication at the start of the extension study.

Exclusion criteria

* Patients with a history of chronic disease of the immune system other than MS.
* Uncontrolled hypertension.
* Patients with active systemic bacterial, viral or fungal infections, positive testing for hepatitis A, B, C and E or HIV (see protocol page 8-9 for details).
* Macular edema.
* Any of the following cardiovascular conditions: MI in the last 6 months, unstable ischemic heart disease, cardiac failure (NYHA Class III), arrhythmia requiring current treatment with Class Ia and III antiarrhythmic drugs, 2nd (Mobitz II) or 3rd degree AV block, increased QTc interval >500 msec.
* Severe pulmonary disease, pulmonary fibrosis, active tuberculosis (see protocol page 9 for details).
* Uncontrolled diabetes mellitus.
* Hepatic conditions (see protocol page 16 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):	10-04-2013
Enrollment:	41
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Gilenya
Generic name:	fingolimod
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	03-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2013
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-03-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-08-2015
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 NCT01779934
EudraCT	EUCTR2012-000835-18-NL
CCMO	NL42677.029.12