A double-blind, randomized, mulicenter, placebo-controlled, parallel-group study comparing the efficacy and safety of 1.25 mg FTY720 administered orally once daily versus placebo in patients with primary progressive multiple sclerosis

Published: 26-09-2008
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON39840

Source
ToetsingOnline

Brief title
CFTY720D2306

Condition

- Autoimmune disorders
- Demyelinating disorders

Synonym
Primair Progressieve Multiple Sclerose

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: bedrijf;zie sectie B

Intervention

Keyword: FTY720, oral, PPMS

Outcome measures

Primary outcome

EFFICACY

25'TWT, EDSS, 9-HPT

Secondary outcome

Safety and tolerability of FTY720; MRI parameters; patient reported outcomes;

pharmacokinetics; pk/pd relationship

Study description

Background summary

At present there is no registered drug available to treat patients with PPMS. FTY720 has shown good results in patients with relapsing-remitting MS. This study will show whether these results can also be achieved in patients with PPMS.

Study objective

The purpose of this study in patients with primary progressive multiple sclerosis (PPMS) is to evaluate
whether FTY720 is effective in delaying MS disability progression in the absence of relapses
compared to placebo. Furthermore, safety and tolerability data will be obtained in these patients.

Study design

A double-blind; randomized, multicenter; placebo-controlled; parallel-group study.

Intervention

One group will receive, once daily, a capsule of FTY 0.5 mg, the other group will receive, once daily, a placebo capsule.

Study burden and risks

Burden:
In a time span of about 4.5 years, patients have to visit the hospital approximately 23 times.
During these visits a variety of measurements/tests is being performed. Some of them to study the efficacy of FTY720 (e.g. 25'TWT, EDSS score, and 9-HPT), others to study the safety of FTY720 in patients with PPMS (e.g. ECG, bloodtests, Chest X-ray, lung function tests, ophthalmology and dermatology tests, bloodpressure).

Risks:
- In previous studies (in a different patient population) bradicardia was observed within 6 hours of first intake. This is why
patients have to stay in hospital for 6 hours after the first intake of study medication in the present study.
- Possible adverse events related to the collection of blood samples (bruising etc)
- Other potential risks as listed in the patient information sheets.

Contacts

Public
Novartis

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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/female, 25 through 65 years of age inclusive
* diagnosis of primary progressive multiple sclerosis (one year of disease progression plus at least two of the following: a) positive brain MRI, b) positive spinal cord MRI, c) positive CSF).
* time since first reported symptoms between 2 and 10 years
* documented evidence of clinical disability progression in the 2 years prior to Screening
* EDSS score of 3.5-6.0 inclusive
* pyramidal functional system score of 2 or more
* 25*TWT less than 30 seconds

Exclusion criteria

* history of MS attack/relapse
* progressive disabling neurological disorder, other than PPMS
* presence of cervical spinal cord compression (on Screening MRI)
* relevant history of vitamin B12 deficit
* history of chronic active disease of the immune system other than MS
* diagnosis of macular edema
* unable to undergo MRI scans

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2008
Enrollment:	57
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	not applicable
Generic name:	Fingolimod
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	26-09-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-10-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-04-2009

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-10-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-11-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-04-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-06-2010

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-04-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-08-2013
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:	19-11-2013

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:	12-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2014
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
EudraCT	EUCTR2007-002627-32-NL
ClinicalTrials.gov	NCT00731692
CCMO	NL18345.029.08