Double-blind, placebo-controlled, randomized, parallel-group Phase II study in subjects with relapsing forms of multiple sclerosis (MS) to evaluate the safety, tolerability, and effects of two doses of CDP323 over 24 weeks with a rater-blind MRI follow-up over 12 weeks.

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Therapeutic exploratory study (Phase II).The purpose of this study the efficacy of a new compound (CPD323) for the treatment of Relapsing Remitting Multiple Sclerose (RRMS).CDP323 is a small chemical molecule. It is taken orally (by mouth) as a...

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

Summary

ID

NL-OMON33867

Source
ToetsingOnline

Brief title
multiple sclerosis-CDP323-22

Condition

- Demyelinating disorders

Synonym
muscle disease, nerve disease

Research involving
Human

Sponsors and support

Primary sponsor: UCB Pharma S.A.
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: MRI follow-up, Relapsing-Remitting Multiple Sclerosis, safety, tolerability

Outcome measures

Primary outcome

Primaire objective.

Compare the effects of 500 mg CDP323 once daily and twice daily on MS-related imaging parameters in subjects with relapsing MS (RMS) with the effects seen under placebo treatment in that population over a period of 24 weeks.

Secondary outcome

Exploratory Objectives

* Compare CDP323's tolerability and safety in RMS subjects with placebo treatment in that population over a period of 24 weeks;

* Compare the effects of CDP323 on the occurrence of relapses in RMS subjects with the effects seen under placebo treatment in that population over a period of 24 weeks;

* Compare the effects of twice daily dosing of CDP323 vs once daily dosing of CDP323 including the related time course of *4/VCAM-1 binding between the two dosing regimen and placebo;

* Characterize the main pharmacokinetic parameters of CDP323 and its metabolites in subjects suffering from RMS.

* Assess potential withdrawal effects after termination of treatment with

CDP323.

Study description

Background summary

The purpose of this study is to find out whether a new drug named CDP323 will reduce inflammation in the brain of patients with MS. The best way to do so is to take frequent pictures of inflamed brain tissue and to decide whether the inflammation can be reduced by CDP323. The pictures are taken with a MRI scanner (Magnetic Resonance Imaging). The study will also check whether CDP323 causes side effects and how much CDP323 is in the blood.

Study objective

Therapeutic exploratory study (Phase II).
The purpose of this study the efficacy of a new compound (CPD323) for the treatment of Relapsing Remitting Multiple Sclerose (RRMS).
CDP323 is a small chemical molecule. It is taken orally (by mouth) as a capsule.
Up to now, 60 healthy volunteers have taken CDP323 in studies. CDP323 was considered to be safe and well tolerated in these studies. Research will now start to see whether CDP323 is effective as a treatment in patients with MS.
This study is multinational and will involve a total of about 317 patients across approximately 70 institutions in Europe and North America.

Study design

The study period is about 40 weeks. Eligibility will be assessed during a 4-week period. After eligibility has been confirmed, subjects will be randomized to one of the three treatment arms and will receive study drug; placebo/CDP323 500mg daily/CDP323 1000 mg daily taken ith water.
The double-blind treatment period will be 24 weeks. After completion of the treatment period (EoT), subjects will undergo a 12-week rater-blind drug-free MRI follow-up in order to evaluate potential rebound effects. All subjects having received study drug will come back to the clinic 12 months after week 40 for follow-up visit.

Intervention

Blood sampling at every visit (inclusive: for women with childbearing potential a urine pregnancy test will be done at every visit),

MRI scan (8x);
Physical examination;
ECG (6x).

Study burden and risks

Visit schedule:
screening (Day 0); wk1;
baseline (wk 4, randomization and SoT);
study visits (including telephone visits): wk 5, wk 6, wk 8, wk 10, wk 13, wk 16, wk 19, wk 22, wk 25
wk 28 = EoT;
follow-up wk 30, wk 34, wk 40 = EoS.
12 months follow up (=wk 80)

There will be done 8 MRI-scans with gadolinium: at screening, baseline and than every 6 weeks.

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

*female and male subjects aged 18-60 years inclusive at time of informed consent;
*diagnosis of MS according to the revised McDonald criteria (Polman et al. Ann Neurol 2005;58:840-6);
*relapsing form of MS, i.e., RRMS or SPMS (with superimposed relapses) according to Lublin and Reingold (Neurology 1996;46:907-11);
*at least one clinical relapse in the 12 months before screening;
*active disease, defined by the presence of either,
* at least nine lesions on the screening T2 scan or,
* Gd enhancement on the screening T1 scan or,
* Gd enhancement on an MRI scan during the past 12 months or,
* at least two new T2 lesions during the past 12 months;
* failed prior treatment with beta-interferons due to lack of efficacy or tolerability;

Exclusion criteria

*type of MS other than relapsing;
*any disease other than MS that could better explain the subject's signs and symptoms;
*any conditions that could interfere with the MRI or any other evaluation in the study;
*any clinically significant disease state or findings other than MS, in particular neoplastic disease or organ transplantation;
*any clinically significant deviation from reference ranges in laboratory tests or any abnormal, clinically significant ECG findings;
*any significant deviation from reference ranges for hepatic function;
*signs of silent infections, including positive tests for HIV1, HIV2, or Hepatitis B or Hepatitis C, or tuberculosis;

Study design

Design

Study phase:	2
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):	05-11-2007
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	geen
Generic name:	geen

Ethics review

Approved WMO Date:	06-03-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-04-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-10-2007
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-01-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-03-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-08-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-10-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-02-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-02-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2009
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	EUCTR2006-002204-33-NL
CCMO	NL15910.029.07