A Phase IIIB, Double Blind, Placebo-Controlled, Multcenter, Parallel Group, Extension Trial to Evaluate the Safety and Tolerability of Oral Cladribine in Subjects with Relapsing-Remitting Multiple Sclerosis Who Have Completed Trial 25643 (Clarity)

Published: 07-04-2008
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Observational invasive

Summary

ID

NL-OMON32113

Source
ToetsingOnline

Brief title
Extension of the Clarity Study/ 27820

Condition

- Demyelinating disorders

Synonym
Multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: IATEC
Source(s) of monetary or material Support: Merck Serono

Intervention

Keyword: Cladribine, Extension, Multiple sclerosis, Relaps

Outcome measures

Primary outcome

Primary parameter: to evaluate the safety and the tolerability of oral

cladribine and to evaluate the effect on the QTc interval.

Safety enpoints:

proportion of subjects with grades 3 or 4 adverse events

proportion of subjects with at least one grade 4 CTC adverse event toxicity

mean change in lab values

incidence of adverse events and serious adverse events

mean change in QTc interval from baseline

Other endpoints:

proportion of subjects relapse free

disability progression assessed at annuals intervals

time to confirmed EDSS progression

MRI endpoints

pharmacoeconomic and health outcomes

For more details : see protocol synopsis page 12 , 13 and 14.

Secondary outcome

Secundary paramaters:

-explore the long term benefit (rate of disease progression as reflected by

rate of change in Expanded Disabiltiy Status Score) of treatment with oral

cladribine vs. placebo.

-explore the relationship between oral cladribine treatments and immunologic

parameters, MRI measurments of disease activities, clinical relapses and

disease progression in subjects previously randomised in trial 25643.

-determinate the benefit of continued oral cladribine treatment on

health-related quality of life and economic outcome measures.

Study description

Background summary

The trial will enrol eligible subjects with Relapsing remitting multiple sclerosis who completed the two year Clarity study.
Patients wil be randomised and receive Placebo or oral Cladribine.

Study objective

The objective of the study is to evaluate the safety of the extended treatment with oral Cladribine and to determinate the effect on the QTc interval.
other objectives:
-explore the long term benefit (rate of disease progression as reflected by rate of change in Expanded Disabiltiy Status Score) of treatment with oral cladribine vs. placebo.
-explore the relationship between oral cladribine treatments and immunologic parameters, MRI measurments of disease activities, clinical relapses and disease progression in subjects previously randomised in trial 25643.
-detrminate the benefit of continued oral cladribine treatment on health-related quality of life and economic outcome measures.
-explore the association between genetic variants, clinical efficacy, MRI

endpoints and groups of subjects with adverse events (grade 3 and 4 toxicity).
- explore the effect of oral cladribine on gene expression profiles.

Study design

A phase IIIB, double-blind, placebo controlled, multicenter, parallel group, extension of the Clarity study.

Study burden and risks

Study duration: 96 weeks.
19 study visits (1 screening visit, study day 1: to dispens treatment and 17 follow-up visits).
MRI scheduled at 5 visits. (study day 1, Week 24, 48, 72 and 96)
Blood and urine sampling at 19 visits.
If the patients consents: additional blood sampling for pharmacogenomics, pharmacogenetics and PK analysis.
ECG scheduled at 5 visits
2 questionnaires: to be completed at 5 visits and in case of a relaps:
-Health related Quality of Life questionnaire
-Health Resource Utilazation questionnaire

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

the patient must have completed his randomized treatment in study 25643 (CLarity)

Exclusion criteria

Abnormal laboratory results indicative of any significant or unstable disease that would preclude the administration of oral Cladribine.
Moderate to several renal disease.
Symptoms suggestive of transmissible spongiform encephalopathy.

Study design

Design

Study phase:	3
Study type:	Observational invasive
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):	21-04-2009
Enrollment:	1
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cladribine
Generic name:	Cladribine

Ethics review

Approved WMO Date:	07-04-2008
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	29-09-2008
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	04-11-2008
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	EUCTR2007-000381-20-NL

Register	ID
CCMO	NL21599.096.08