A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Comparison Study to Determine the Efficacy and Safety of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis

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North America, Europe, and rest of worldThe primary objective of this study is to determine whether BG00012, when compared with placebo, is effective in reducing the proportion of relapsing subjects at 2 years.The secondary objectives of this study...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Interventional

Summary

ID

NL-OMON31459

Source
ToetsingOnline

Brief title
N/A

Condition

- Central nervous system infections and inflammations

Synonym
multiple sclerosis

Research involving

Human

Sponsors and support

Primary sponsor: Biogen Idec Ltd.
Source(s) of monetary or material Support: Biogen Idec

Intervention

Keyword: BG00012, Relapsing-Remitting Multiple Sclerosis

Outcome measures

Primary outcome

The primary analysis will be a Cox proportional hazards model for time to first relapse. The proportion of subjects relapsed at 2 years will be estimated from the Kaplan-Meier survival curve distribution.

Secondary outcome

Annualized relapse rate at 1 year will be analyzed using Poisson regression.

Disability progression as measured by EDSS will be analyzed using a Cox proportional hazards model.

The number of new or newly enlarging T2 hyperintense lesions and Gd-enhancing lesions will be analyzed using multiple logit regression.

Study description

Background summary

A Phase 2, double-blind, placebo-controlled, dose-finding, safety and efficacy study in 257 subjects with relapsing-remitting multiple sclerosis (RRMS) (Study C 1900) demonstrated that BG00012 (dimethyl fumarate [DMF]) significantly

reduced Gd enhancing on brain magnetic resonance imaging (MRI) after 6 months. The drug was well tolerated at the three doses that were tested. The combination of a potential immunomodulatory effect of DMF with its safety and efficacy profile from the Phase 2 RRMS study support further study of its clinical efficacy in the management of RRMS.

Study objective

North America, Europe, and rest of world
The primary objective of this study is to determine whether BG00012, when compared with placebo, is effective in reducing the proportion of relapsing subjects at 2 years.
The secondary objectives of this study are:
1. To determine whether BG00012, when compared with placebo, is effective in:
* reducing the total number of new or newly enlarging T2 hyperintense lesions on brain MRI scans in a subset of subjects at 2 years;
* reducing the total number of Gd-enhancing lesions on 3 brain MRI scans taken over 2 years in a subset of subjects;
* reducing the rate of clinical relapses at 1 year;
* slowing the progression of disability at 2 years as measured by at least a 1.0 point increase on the EDSS from baseline EDSS >=1.0 that is sustained for 12 weeks, or at least a 1.5 point increase on the EDSS from baseline EDSS = 0 that is sustained for 12 weeks.

Study design

Multicenter, parallel-group, randomized, placebo-controlled, double-blind, dose-comparison study

Intervention

-group 1
337 subjects will receive BG00012, 240mg BID (2 capsules/120mg twice a day) and 2 placebo capsules once a day

-group 2
337 subjects will receive BG00012, 240mg TID (2 capsules/120mg each 3 times a day)

-group 3
337 subjects will receive placebo 2 capsules 3 times daily

Study burden and risks

The most commonly observed events were flushing, PS relapse, nasopharyngitis,

headache, nausea, diarrhea, fatigue, pruritis, upper abdominal pain, influenza, and hot flush.

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

-written informed consent
-aged 18 to 55 years old
-confirmed diagnosis of relapsing-remitting multiple sclerosis
-baseline EDDS between 0.0 and 5.0 inclusive (expanded disability status scale)
-must have experienced at least 1 relapse within the 12 months prior to randomization

Exclusion criteria

-primary progressive, secondary progressive, or progressive elapsing MS
-unable to perform the Timed 25-Foot Walk, Nine-Hole Peg Test (9HTP) with both upper extremities, and PASAT 3
-unable to perform visual function tests
-history of malignancy
-history of severe allergic of anaphylactic reactions or known drug hypersensitivity

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):	11-11-2008
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	dimethyl fumarate

Ethics review

Approved WMO Date:	26-03-2007
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	20-07-2007
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	16-06-2008
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	27-06-2008
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	24-09-2008
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	24-08-2009
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	06-10-2009
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	16-08-2010
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	EUCTR2006-003696-12-NL
CCMO	NL16020.096.07