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A Safety and Efficacy Study of Oral Cladribine in Subjects With Relapsing-remitting Multiple Sclerosis (RRMS) (CLARITY)

ClinicalTrials.gov ID NCT00213135

Sponsor EMD Serono

Information provided by EMD Serono (Responsible Party)

Last Update Posted 2014-02-07

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to determine if cladribine tablets are a safe and effective treatment for relapsing-remitting multiple sclerosis (RRMS).

Detailed Description

This is a randomized, double-blind, three-arm, placebo-controlled, multi-center study. The study includes a pre-study evaluation period (up to 28 days prior to the start of treatment); an initial treatment period from Week 1 to 48; and a re-treatment period during Week 49 to 96.

During the initial treatment period (Week 1 to 48), eligible subjects are equally randomized by a central randomization system to receive either a) cladribine at a low dose (0.875 milligram per kilogram per course [mg/kg/course] for two courses plus placebo for two courses); b) cladribine at a high dose (0.875 mg/kg/course for four courses); or c) placebo (four courses). During the re-treatment period (Weeks 49 to 96), subjects received either a) cladribine at a low dose (0.875 mg/kg/course for two courses); or b) placebo (two courses).

For all randomized subjects, there is a rescue option of treatment with Rebif® (interferon beta-1a 44 microgram (mcg) given subcutaneously three times a week), if the subject experienced more than one qualifying relapse, and/or experienced a sustained increase in their EDSS score of greater than or equal to (>=) 1 point, or >=1.5 points if baseline EDSS score is 0, (over a period of three months or greater), during a calendar year beginning at Week 24.

To maintain the blind, there is a treating physician who view clinical laboratory results and assess adverse events and safety information, and an independent blinded evaluating physician who will perform neurological exams. A central neuroradiology center, also blinded to treatment, will assess magnetic resonance imaging (MRI) evaluations.

Official Title

A Phase III, Randomized, Double-blind, Three-arm, Placebo-controlled, Multi-center Study to Evaluate the Safety and Efficacy of Oral Cladribine in Subjects With Relapsing-remitting Multiple Sclerosis (RRMS)

Conditions

Multiple Sclerosis, Relapsing-Remitting

Intervention / Treatment

- Drug: Cladribine 5.25 mg/kg
- Drug: Cladribine 3.5 mg/kg
- Other: Placebo

Other Study ID Numbers

- 25643

Study Start

2005-04

Primary Completion (Actual)

2008-11

Study Completion (Actual)

2008-11

Enrollment (Actual)

1326

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus Genetics (https://medlineplus.gov/genetics/) related topics: Multiple sclerosis (https://medlineplus.gov/genetics/condition/multiple-sclerosis)

MedlinePlus (https://medlineplus.gov/) related topics: Multiple Sclerosis (https://medlineplus.gov/multiplesclerosis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Cladribine (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Cladribine)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Male or female, between 18 and 65 years of age (inclusive, at time of informed consent)
- Has definite MS according to the McDonald criteria
- Has relapsing-remitting disease with 1 or more relapses within 12 months prior to Study Day 1
- Must have been clinically stable and not has a relapse within 28 days prior to Study Day 1
- Has MRI consistent with MS at the pre-study evaluation according to the Fazekas criteria
- Has a EDSS score from 0 to 5.5, inclusive
- Weighed between 40-120 kilogram (kg), inclusive
- If female, she must:
    1. be post-menopausal or surgically sterilized; or
    2. uses a hormonal contraceptive, intra uterine device, diaphragm with spermicide, or condom with spermicide, for the duration of the study; and
    3. be neither pregnant nor breast-feeding
- If male, he must be willing to use contraception to avoid pregnancies
- Be willing and able to comply with study procedures for the duration of the study
- Voluntarily provides written informed consent, and for United states of America (USA) sites only, a subject authorization under Health Insurance Portability and Accountability Act (HIPAA)

Exclusion Criteria:

- Has secondary progressive MS (SPMS) or primary progressive MS (PPMS)
- Prior use of disease modifying drugs (DMDs) within the last 3 months, or 2 or more prior treatment failures with DMDs on the basis of efficacy
- Has significant leukopenia (white blood cell count less than 0.5 times the lower limit of normal of the central laboratory) within 28 days prior to Study Day 1
- Has received cladribine, mitoxantrone, total lymphoid irradiation, myelosuppressive therapy, campath-1h, cyclophosphamide, azathioprine, methotrexate or natalizumab
- Has received oral or systemic corticosteroids or adrenocorticotropic hormone within 28 days prior to Study Day 1
- Has compromised immune function or infection
- Has received oral or systemic corticosteroids or adrenocorticotropic hormone within 28 days prior to Study Day 1
- Has received cytokine-based therapy, intravenous immunoglobulin therapy, or plasmapheresis within 3 months prior to Study Day 1
- Has platelet and absolute neutrophil counts below the lower limit of normal range within 28 days prior to Study Day 1
- Has prior or current history of malignancy
- Has a history of persistent anemia, leukopenia, neutropenia, or thrombocytopenia after immunosuppressive therapy
- Has systemic disease that, in the opinion of the Investigator, might interfere with subject safety, compliance or evaluation of the condition under Study (for example, insulin-dependent diabetes, Lyme disease, clinically significant cardiac, hepatic, or renal disease, Human Immunodeficiency Virus, or Human T-Cell Lymphotrophic Virus Type-1)
- Has a psychiatric disorder that, in the opinion of the Investigator, was unstable or would preclude safe participation in the study
- Has allergy or hypersensitivity to gadolinium, to cladribine or any of its excipients
- Has used any investigational drug or experimental procedure within 6 months prior to Study Day 1

Ages Eligible for Study

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Triple (Participant, Care Provider, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Cladribine 5.25 mg/kg	Drug: Cladribine 5.25 mg/kg • Cladribine tablet will be administered as cumulative dose of 0.875 milligram per kilogram (mg/kg) over a course of 4 or 5 consecutive days of 28-day period at Week 1, 5, 9, 13, 48, and 52 resulting in total cladribine dose of 5.25 mg/kg during the treatment period of 96 weeks.
Experimental: Cladribine 3.5 mg/kg	Drug: Cladribine 3.5 mg/kg • Cladribine tablet will be administered as cumulative dose of 0.875 mg/kg over a course of 4 or 5 consecutive days of 28-day period at Weeks 1, 5, 48, and 52 and placebo matched to cladribine tablet will be administered at Week 9 and 13 resulting in total cladribine dose of 3.5 mg/kg during the treatment period of 96 weeks.
Placebo Comparator: Placebo	Other: Placebo • Placebo matched to cladribine tablet will be administered over a course of 4 or 5 consecutive days of 28-day period at Weeks 1, 5, 9, 13, 48 and 52 during the treatment period of 96 weeks.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Annualized Qualifying Relapse Rate	A qualifying relapse was defined as an increase of 2 points in at least one functional system of the expanded disability status scale (EDSS) or an increase of 1 point in at least two functional systems (excluding changes in bowel or bladder function or cognition) in the absence of fever, lasting for at least 24 hours and to have been preceded by at least 30 days of clinical stability or improvement. Expanded disability status scale (EDSS) assesses disability in 8 functional systems. An overall score ranging from 0 (normal) to 10 (death due to multiple sclerosis [MS]) was calculated. The annualized relapse rate for each treatment group was calculated as the total number of confirmed relapses divided by the total number of days on study multiplied by 365.25.	Week 96

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Relapse-free Participants	A qualifying relapse was defined as an increase of 2 points in at least one functional system of the EDSS or an increase of 1 point in at least two functional systems (excluding changes in bowel or bladder function or cognition) in the absence of fever, lasting for at least 24 hours and to have been preceded by at least 30 days of clinical stability or improvement. Expanded disability status scale (EDSS) assesses disability in 8 functional systems. An overall score ranging from 0 (normal) to 10 (death due to MS) was calculated.	Week 96
Time to Disability Progression	Time to disability progression was defined as the time to a sustained increase in EDSS score of at least 1 point if baseline EDSS score between 0.5 and 4.5 inclusively, or at least 1.5 points if the baseline EDSS score was 0, or at least 0.5 point if the baseline EDSS score was at least 5, over a period of at least three months. Expanded disability status scale (EDSS) assesses disability in 8 functional systems. An overall score ranging from 0 (normal) to 10 (death due to MS) was calculated. Tenth Percentile of time to sustained increase in EDSS score was reported using Kaplan-Meier survival curve.	Baseline up to Week 96
Mean Number of Combined Unique (CU) Lesions, Active Time Constant 2 (T2) Lesions, and Active	Mean Number of CU lesions, active T2 lesions, and active T1 Gd+ lesions were measured by using magnetic resonance imaging (MRI) scans.	Week 96

Time Constant 1 (T1) Gadolinium-Enhanced (Gd+) Lesions Per Participant Per Scan		

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

EMD Serono

Collaborators

No information provided

Investigators

- Study Director: Steven J. Greenberg, M.D., EMD Serono

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2005-09-13

First Submitted that Met QC Criteria

2005-09-13

First Posted (Estimated)

2005-09-21

Results Reporting Dates

Results First Submitted

2013-09-30

Results First Submitted that Met QC Criteria

2013-09-30

Results First Posted (Estimated)

2013-12-02

Study Record Updates

Last Update Submitted that met QC Criteria

2014-01-10

Last Update Posted (Estimated)

2014-02-07

Last Verified

2014-01

More Information

Terms related to this study

Additional Relevant MeSH Terms

Pathologic Processes
Demyelinating Autoimmune Diseases, CNS
Autoimmune Diseases of the Nervous System
Nervous System Diseases
Demyelinating Diseases
Autoimmune Diseases
Immune System Diseases
Multiple Sclerosis
Multiple Sclerosis, Relapsing-Remitting
Sclerosis
Antineoplastic Agents
Immunosuppressive Agents
Immunologic Factors
Physiological Effects of Drugs
Cladribine

Study Documents

No study documents available

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A Safety and Efficacy Study of Oral Cladribine in Subjects With Relapsing-remitting Multiple Sclerosis (RRMS) (CLARITY)

ClinicalTrials.gov ID NCT00213135

Sponsor EMD Serono

Information provided by EMD Serono (Responsible Party)

Last Update Posted 2014-02-07

Record History Tab

Study Record Versions

- This table shows the list of all the versions of this study record arranged in order by date.
- The first column shows the date the study record was updated, and the second column shows the elements in the study record that were changed.
  - To view a version of a study record, click the version date.
  - To compare versions, select two versions using the check boxes and click the "Compare" button at the bottom of the list.

☐	2005-09-13	None (earliest version on record)
☐	2005-11-15	Study Status Study Identification
☐	2006-02-02	Study Status Contacts/Locations
☐	2006-03-22	Study Status
☐	2006-05-17	Study Status Study Identification
☐	2006-08-01	Study Status Contacts/Locations
☐	2006-08-31	Study Status

Compare

		Outcome Measures Study Identification Study Design
☐	2006-10-05	Study Status Contacts/Locations
☐	2006-12-06	Recruitment Status Study Status
☐	2007-04-10	Study Status Outcome Measures Contacts/Locations
☐	2007-04-13	Study Status Study Design Outcome Measures
☐	2007-05-29	Study Status Conditions Study Design Outcome Measures
☐	2008-01-16	Study Status Study Identification Study Description Conditions Study Design Arms and Interventions Eligibility Contacts/Locations Sponsor/Collaborators
☐	2008-09-29	Study Status Study Design
☐	2009-03-21	Study Status
☐	2009-12-11	Recruitment Status Study Identification Study Status Arms and Interventions Contacts/Locations Sponsor/Collaborators
☐	2011-08-05	Study Status References

		Study Identification Study Description Arms and Interventions Eligibility
☐	2012-01-27	Study Status Sponsor/Collaborators
☐	2013-09-30	Study Status Outcome Measures Baseline Characteristics Study Identification Study Description Arms and Interventions Eligibility Participant Flow Adverse Events More Information
☐	2014-01-10	Study Status Outcome Measures Baseline Characteristics
	Date	**Changes**

Version 13: 2008-01-16

Study Details

Study Identification

Unique Protocol ID
25643

Brief Title
CLARITY - Safety and Efficacy of Oral Cladribine in Subjects With Relapsing-Remitting MS

Official Title
A Phase III, Randomized, Double-Blind, Three-Arm, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Oral Cladribine in Subjects With Relapsing-Remitting Multiple Sclerosis

Date **Changes**

Study Status

Record Verification
2008-01

Overall Status
Active, not recruiting

Study Start
2005-01

Primary Completion
2008-12 [Estimated]

Study Completion

First Submitted
2005-09-13

First Submitted that Met QC Criteria
2005-09-13

First Posted
2005-09-21

Last Update Submitted that Met QC Criteria
2008-01-16

Last Update Posted
2008-01-17 [Estimated]

Sponsor/Collaborator

Sponsor
EMD Serono

Responsible Party

Collaborators

Date	Changes

U.S. FDA-regulated Drug

U.S. FDA-regulated Device

Data Monitoring

Study Description

Brief Summary

The purpose of the study is to determine if cladribine is a safe and effective treatment for relapsing-remitting MS

Detailed Description

This will be a randomized, double-blind, three-arm, placebo-controlled, multi-center study. The study will include a pre-study evaluation period (up to 28 days prior to the start of treatment); an initial treatment period during Year 1; and a retreatment period during Year 2.

During the initial treatment period in Year 1, eligible subjects will be equally randomised by a central randomisation system to receive either a) cladribine at a low dose (0.875 mg/kg/cycle for two cycles + placebo for two cycles); b) cladribine at a high dose (0.875 mg/kg/cycle for four cycles); or c) placebo (four cycles). During the retreatment period in Year 2, subjects will receive either a) cladribine at a low dose (0.875 mg/kg/cycle for two cycles); or b) placebo (two cycles).

For all randomized subjects, there will be a rescue option of treatment with Rebif (44 mcg three times a week (tiw)) if the subject experiences more than one qualifying relapse, and/or experiences a sustained increase in their EDSS of ³one point, or ³1.5 points if baseline EDSS was 0, (over a period of three months or greater), during a calendar year beginning at Week 24.

To maintain the blind, there will be a Treating Physician who will view clinical laboratory results and assess AEs and safety information, and an independent blinded Evaluating Physician who will perform neurological exams. A central neuroradiology center, also blinded to treatment, will assess MRI evaluations.

Conditions

Condition

Multiple Sclerosis, Relapsing-Remitting

Keywords

Study Design

Study Type

Interventional

Primary Purpose

Treatment

Study Phase

Phase 3

Interventional Study Model

Parallel Assignment

Interventional Model Description

Number of Arms

3

Masking

Triple (Participant, Care Provider, Investigator)

Masking Description

Allocation

Randomized

Enrollment

1290 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: Cladribine • Cladribine low dose (0.875 mg/kg/cycle)
Experimental: 2	Drug: Cladribine • Cladribine high dose (0.875 mg/kg/cycle)
Placebo Comparator: 3	Other: Placebo • Placebo

Outcome Measures

Primary Outcome Measures

1. To evaluate the efficacy of cladribine versus placebo in the reduction of qualifying relapse rate during 96 weeks of treatment in subjects with RRMS.
   [Time Frame: During 96 weeks]

Secondary Outcome Measures

1. To assess the effect of cladribine on progression of disability in subjects with RRMS
   [Time Frame: At 96 weeks]

Eligibility

Minimum Age

18 Years

Maximum Age

65 Years

Sex

All

Accepts Healthy Volunteers

No

Criteria

Inclusion Criteria:

- 18 -65 years of age
- Definite MS according to the McDonald criteria
- Relapsing-remitting disease with 1 or more relapses within 12 months
- No relapse within 28 days
- MRI consistent with MS
- EDSS from 0-5.5
- Weigh between 40-120 kg
- Males and females must use contraception

Exclusion Criteria:

- Pregnant or breast feeding
- Secondary Progressive MS (SPMS) or Primary Progressive MS (PPMS)
- Prior use of disease modifying drugs (DMDs) within the last 3 months, or 2 or more prior treatment failures with DMDs
- Compromised immune function or infection, or prior use of medications that altered the immune system
- Significant clinical or laboratory abnormalities at the screening visit (abnormal platelet, neutrophil or white blood cell counts)
- Prior or current history of malignancy
- History of blood disorders after immunosuppressive therapy
- Systemic disease or psychiatric disorder that might interfere with subject safety, compliance or evaluation of MS
- Use of any investigational drug or experimental procedure within 6 months

Contacts/Locations

Central Contact Person

Study Officials

- Name
  Steven Greenberg, M.D.

  Role
  Study Director

  Affiliation
  EMD Serono

Location

- **Geneva, Switzerland**

  Facility:
  Local Medical Information Office

IPD Sharing

Available IPD/Information

IPD information

References

Citations

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Links

Document Section