COMPLETED

# 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)

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

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<br>• 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<br>• 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<br>• 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. |

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