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)

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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 • 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.

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