

MS CLINICAL TRIALS CURRENTLY ENROLLING

Title: A Multicenter Double-Blind Randomized Study Comparing the Combined Use of Interferon Beta-1a and Glatiramer Acetate to Either Agent Alone in Patients with Relapsing Remitting Multiple Sclerosis (**CombiRx**)

PI: Ann Camac, MD
Study Coordinator: Sharon Lamont 781-372-7196

Summary: The CombiRx study is being done to determine whether *combined* treatment with interferon beta-1a (INF-b) IM (Avonex) once weekly and glatiramer acetate (GA) SQ (Copaxone) daily is more effective than either agent alone in treating relapsing remitting MS. Patients will be randomized to one of three arms:

- Arm 1: **Active** interferon beta-1a and **Active** glatiramer acetate (50% of the patients)
- Arm 2: **Active** interferon beta-1a and **Placebo** glatiramer acetate (25% of the patients)
- Arm 3: **Placebo** interferon beta-1a and **Active** glatiramer acetate (25% of the patients)

Patient Population:

- Male and female subjects aged 18 to 60, inclusive
- Relapsing-Remitting MS
- Expanded Disability Status Scale (EDSS) score between 0 and 5.5, inclusive
- At least 2 exacerbations in the prior three years; one exacerbation may utilize the McDonald MRI criteria for dissemination in time (a new Gd-enhancing lesion demonstrated on a scan done at least 3 months following onset of a clinical attack or a new T2 lesion or Gd-enhancing lesion on a follow-up scan after an addition 3 months)

CURRENTLY ENROLLING

Title: NINDS Biomarkers in Multiple Sclerosis Study (BioMS)

PI: Ann Camac, MD
Study Coordinator: Sharon Lamont 781-372-7196

Summary: Patients participating in the CombiRx study have the option to also participate in the BioMS study, a sub-study. This study is designed to search for genes and proteins that may allow a better understanding of 1) which factors determine disease course, 2) who is going to respond to which medications 3) whether certain genes or proteins can allow us to predict more benign or severe disease course. Blood is collected 4 times for this sub-study, coinciding with CombiRx visits (at Baseline, Month 6, Month 12, and Month 36).

CURRENTLY ENROLLING

Title: Multi-center, open-label study to evaluate the effects of natalizumab (TYSABRI®) treatment on fatigue and cognition in subjects with relapsing forms of Multiple Sclerosis (MS). (**ENER-G**)

PI: Claudia Chaves, MD
Study Coordinator: Sharon Lamont 781-372-7196

Summary: The purpose of this study is to evaluate the effects of Tysabri® treatment on fatigue and cognition in patients with relapsing forms of Multiple Sclerosis (MS).

Patient Population:

- MS patients enrolled in the TOUCH prescribing program still naïve to Tysabri® treatment.
- Recent MRI as part of the TOUCH™ prescribing program.
- Patient must be between 18 and 55 years of age.
- EDSS between 0 and 3.5

- Capable of completing the fatigue (MFIS, FSS, and VAS-F) and cognition (ANAM) sessions. All scales are patient self-assessed and computerized.

CURRENTLY ENROLLING

Title: Prediction of disability and neuropsychological impairment in multiple sclerosis: comparison of conventional magnetic resonance imaging measures of atrophy and lesion burden.

PI: Claudia Chaves, MD

Study Coordinator: Sharon Lamont 781-372-7196

Summary: Brain MRIs will be analyzed using a new software application (Java image software, Xinapse Systems, Northants, UK) which contains the tools needed for quantitative analysis for assessment of T2 and T1 burden of disease and measurements of cerebral atrophy (brain parenchymal fraction, third ventricle width, bicaudate ratio, corpus callosum volume). Results will be correlated with the Expanded Disability Status Scale (EDSS) and neuropsychological testing.

Patient Population:

- relapsing remitting MS
- secondary progressive MS
- clinically isolated syndrome
- patients who can tolerate a high field MRI (1.5 Tesla or above)
- no MS relapse or corticosteroid use within the past 6 weeks

CURRENTLY ENROLLING

Title: A Phase 3, Randomized, Rater-and Dose-Blinded Study Comparing Two Annual Cycles of Intravenous Low- and High-Dose Alemtuzumab to Three-Times Weekly Subcutaneous Interferon Beta-1a(Rebif®) in Patients with Relapsing-Remitting Multiple Sclerosis Who Have Relapsed On Therapy (PROTOCOL CAMMS32400507)

PI: Mary Anne Muriello, MD

Study Coordinator: Sharon Lamont 781-372-7196

Summary: The primary objective of this study is to compare the safety and efficacy of 2 annual cycles of either low-dose (12 mg/day) or high-dose (24 mg/day) intravenous (IV) alemtuzumab to 3 times weekly subcutaneous (SC) interferon beta-1a (Rebif®) in patients with active relapsing remitting multiple sclerosis (RRMS) who have experienced at least one relapse while on disease-modifying drug therapy for ≥ 6 months. Efficacy will be measured in co-primary endpoints: time to sustained accumulation of disease and relapse rate.

Patient Population:

- (1) Age 18 to 50 years old (inclusive)
- (2) Diagnosis of MS per update of McDonald criteria¹
- (3) Onset of MS symptoms within 5 years of screening
- (4) EDSS score 0.0 to 5.0
- (5) ≥ 2 MS attacks (first episode or relapses) occurring in the 2 years prior to screening, with ≥ 1 attack in the 1 year prior to screening
- (6) ≥ 6 months continuous treatment with beta interferon or glatiramer acetate during the past 5 years prior to screening.
- (7) ≥ 1 MS attack (relapse) during treatment with interferon beta or glatiramer acetate after being on that therapy for at least 6 months; relapses that occur within 6 months of initiating treatment with interferon beta or glatiramer acetate do not qualify as a relapse during treatment
- (8) MRI scan demonstrating white matter lesions attributable to MS **and** meeting at least one of the following criteria, as determined by the treating neurologist
 - ≥ 9 T2 lesions at least 3 mm in any axis
 - a gadolinium-enhancing lesion at least 3 mm in any axis plus ≥ 1 brain T2 lesions
 - a spinal cord lesion consistent with MS plus ≥ 1 brain T2 lesions

CURRENTLY ENROLLING

Title: Examination of the Genetic Basis of Multiple Sclerosis

PI: Claudia Chaves, MD

Study Coordinator: Sharon Lamont 781-372-7196

Summary: The main objective of this study is to determine the genetic basis of demyelinating diseases, particularly Multiple Sclerosis (MS), by performing a whole, genome-wide scan of DNA haplotypes. Phenotype information will be derived from medical record review, MRI data, conventional immunological characterization, and mRNA analysis using microarray technology.

Patient Population:

Subjects with demyelinating disease:

- Male or Female over the age of 18
- Diagnosed with demyelinating disease including
 - Multiple Sclerosis (MS)
 - Acute Disseminated Encephalomyelitis (ADEM)
 - Clinically isolated syndrome (CIS)
 - Neuromyelitis Optica (NMO)

Biological Parents and Healthy Controls:

- Male or Female over the age of 18

CURRENTLY ENROLLING

MS TRIALS ONGOING, BUT CLOSED TO ENROLLMENT

Title: A Randomized, Controlled Parallel Group Study to Evaluate the Effect of Regularly Scheduled Neutralizing Antibody Testing on Treatment Patterns vs. Usual Care in High-Dose Interferon Treated Subjects

PI: Claudia Chaves, MD

Study Coordinator: Sharon Lamont 781-372-7196

Summary: The presence of certain antibodies in the blood may reduce the effectiveness of MS drugs. This study will determine whether regular blood tests for neutralizing antibody to Rebif and Betaseron will result in treatment changes.

ENROLLMENT CLOSED

Title: Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of Oral Fampridine-SR (10mg B.I.D.) in Patients with Multiple Sclerosis. (**MS-F204**)

PI: Ann Camac, MD

Study Coordinator: Sharon Lamont 781-372-7196

Summary: This study is designed to investigate the safety and efficacy of Fampridine-SR (10 mg oral tablet taken twice a day) in the treatment of people with multiple sclerosis to improve disease related physical disability such as walking, leg strength, and related activities of daily living.

ENROLLMENT CLOSED

Title: Open-Label Extension Study to Evaluate the Safety, Tolerability and Activity of Oral Fampridine-SR in Patients with Multiple Sclerosis who Participated in the MS-F204 Trial (**MS-F204 ext**)

PI: Ann Camac, MD

Study Coordinator: Sharon Lamont 781-372-7196

Summary: Only patients who have completed the previous Fampridine trial (MS-F204) listed are eligible for this study. It allows those patients to continue treatment with open label Fampridine-SR at a dose of 10 mg b.i.d for up to 36 additional months or until it becomes commercially available, whichever comes first.

ENROLLMENT CLOSED

Title: Real-World Betaseron® Outcomes Study (**ROBUST**): A twelve-month, U.S. prospective, observational, open-label, single-arm, multi-center outcomes study of Interferon β -1b (Betaseron®) given every other day for relapsing forms of multiple

PI: Claudia Chaves, MD

Study Coordinator: Sharon Lamont 781-372-7196

Summary: Patients newly prescribed Betaseron® are eligible for this study. The purpose of this study is to collect information regarding patients' responses to Betaseron® to learn if the drug is beneficial and how it affects daily life. Also, to collect the physician's opinion, based on measurements of disease severity, functional status, relapse, and major resource utilization. This study is an "observational" study, meaning participants will not have any medical procedures done that are specific to the study. Participants will only be asked to complete questionnaires.

ENROLLMENT CLOSED

Title: MAESTRO-03: A Double-Blind, Placebo, Controlled Multi-Center Study, to Evaluate the Efficacy and Safety of MBP8298 in Subjects with Secondary Progressive Multiple Sclerosis

PI: Ann Camac, MD

Study Coordinator: Junius Beebe 781-744-5601

Summary: The purpose of the study is to evaluate the safety and effectiveness of MBP8298 when compared to a placebo. More specifically, 500 mg MBP8298 given intravenously every six months for a period of two years, to placebo, in subjects diagnosed with SPMS who are positive for the HLA DR2 and/or DR4 haplotype.

ENROLLMENT CLOSED
