WHAT IS ASCLEPIOS?

ASCLEPIOS is a clinical research study evaluating if an injectable study drug is more effective at treating relapsing MS than an oral medication that is currently being used in treatment.

Participants will be treated with both a daily pill and a monthly injection (following three initial weekly injections). Participants will receive either the investigational treatment, or the comparing treatment. Participants receiving the study drug will take a daily placebo pill with no active ingredient. Participants receiving the comparing treatment will receive monthly placebo injections that do not contain an active ingredient. Neither you, nor your doctor, will know which treatment you are receiving. If you qualify and choose to join the study, you will be asked to participate for a maximum of 2½ years.

WHO CAN JOIN THE ASCLEPIOS STUDY?

You may be able to join ASCLEPIOS if you:

• Are 18 to 55 years of age
• Have been diagnosed with relapsing multiple sclerosis
• Have had at least one MS relapse during the previous year, or two MS relapses in the previous two years
OR
Have had an MRI within the last year that showed disease activity

WHAT WILL I BE ASKED TO DO?

If you qualify for the study and agree to participate, you will be asked to attend a number of appointments and telephone calls with the study doctor for a maximum of 2½ years. These will allow the study doctor to collect the information needed, and more importantly, see how you are doing and monitor your MS.

During these visits, the study doctor will:

• Talk about your symptoms and any changes since your last visit or telephone call
• Conduct a physical exam
• Check your weight and vital signs
• Ask if you are taking any new medications
• Perform study-related assessments (including an MRI scan once a year)
• Collect samples for routine labs (eg, urine sample, blood test)
• Ask you to complete questionnaires
• Review your Patient Diary
• Give you study medication

To learn if you may qualify for ASCLEPIOS, talk to your MS doctor.
WHAT ARE CLINICAL RESEARCH STUDIES?

Clinical research studies are done to better understand the safety of an investigational procedure or medication and how it works in the body. Clinical trials are necessary to develop new medicines and treat conditions such as multiple sclerosis. Qualified doctors run clinical trials. They are responsible for the study-related care of the people who join.

WHAT IS AN INFORMED CONSENT FORM (ICF)?

The Informed Consent Form (ICF) describes the study and any potential risks or benefits of participation. The study doctor will answer any questions you may have. By signing the form, you agree to be part of the study.

FOR MORE INFORMATION:

Frances Devlin
Fdevlin@rmmsc.com
(801) 408-4584

WHY SHOULD I JOIN ASCLEPIOS?

If you qualify and agree to participate in ASCLEPIOS, you will help doctors and researchers gather important information on the study drug and its effect on those with relapsing MS. If you qualify to participate in the study, you will receive the study medication and study-related medical care at no cost.

WILL MY PRIVACY BE PROTECTED?

Study doctors and their staff will respect the privacy of all patients who take part in the study. Details about your health will be kept as confidential as possible. Information on how your health information is collected and kept private is explained in the Informed Consent Form.