UCI Medical Center Clinical Trials Web Page
Standard Research Recruitment Advertisement Format

Note: This form must be submitted to the IRB for approval either as part of a new protocol application or with a request for modification to an IRB-approved protocol (electronic Protocol Modification (e-mod) Request can be found at www.rgs.uci.edu/hs/mod). When you have received approval from the IRB for the advertisement text, please provide a stamped copy to Leanne Spaide, UCI Medical Center, Marketing and Public Relations Department, Rt. 163A, fax (714) 456-8968, for posting on the www.ucihealth.com clinical trials Web page.

1. Lead Researcher: Gaby Thai M.D.

2. Study Title: Multi-center, randomized, double-blind, placebo-controlled, parallel-group, 9 month, equivalence trial comparing the efficacy and safety and tolerability of GTR (Synthon BV) to Copaxone® (Teva) in subjects with relapsing remitting multiple sclerosis followed by an open-label 15 month GTR treatment part evaluating the long-term GTR treatment effects.

3. Purpose of Study: The purpose of this study is to demonstrate the effectiveness of an investigational drug named GTR compared to Copaxone® in patients with relapsing remitting multiple sclerosis (RRMS) and to evaluate the safety and tolerability of GTR injections in comparison to Copaxone®. GTR, glatiramer acetate, is a generic form of Copaxone®. In addition to GTR and Copaxone®, participants may also receive placebo (injection fluid without the active study drug), to help show that both study drugs are working as desired.

4. Eligibility:
You can participate in this study if you:

1. Are between 18-55 years of age and able to provide your written consent.
2. Have been diagnosed with RRMS and have experienced at least one relapse within one year before the Screening Visit.
3. Are a female of childbearing potential you must agree to practice contraceptive methods, as assessed by the study doctor
4. Are able to walk unassisted

You cannot participate in this study if you:

1. Have a life-threatening or pre-existing medical condition that may interfere with your participation in this study.
2. Are pregnant or breastfeeding.
3. Are unable to undergo an MRI, e.g. due to claustrophobia (fear of being in small spaces), metal implants or fragments, tattoos or permanent make-up.
4. Have a known allergy gadolinium containing products (contrast agent), glatiramer acetate or mannitol.
5. Have previously been treated with Copaxone® (glatiramer acetate).

(Please note this is only a partial list of the eligibility criteria for this study).

5. Location (if other than UCIMC): University of California, Irvine Campus in Irvine, CA. MRIs will be performed at Newport Diagnostic Center in Newport Beach, CA.

6. Time Commitment:

Double-blind period – This period will be approximately 9 months. During this part of the study subjects will receive either GTR, Copaxone®, or placebo.

Open-label Period – This period will be approximately 15 months. During this part of the study <u>all subjects</u> will receive 20 mg daily of GTR.

7. Anticipated Benefits (if any): Taking part in this study may or may not help you directly. The researchers hope to show that GTR is equivalent to the approved Copaxone®. During your participation in this study, your study doctor will closely follow your condition. This study will help researchers learn more about the GTR study medication, and it is hoped that this information will help in the treatment of future patients with RMMS.

8. Compensation (if any): You will receive $30 for completing each study visit over the course of the study. There may be up to 15 scheduled study visits. Total compensation for participation in the entire study is up to $450.

9. Contact Name, UCI Department, Phone Number and E-mail:

Shari Niswonger RN (949) 824-8116 or Shari.niswonger@uci.edu

IRB Approval Granted on: