

MS Trials conducted at FMC by Dr. Mark Slee, Neurologist

FMC in conjunction with other public teaching hospitals, both nationally and internationally, conduct trials to test the effectiveness of new treatments.

Patients may be invited to take part in a trial when attending an outpatient appointment, in the Emergency Department as they are admitted to the hospital, or once in hospital as an inpatient.

All research trials conducted at FMC must be approved by the [Southern Area Health Service / Flinders University Human Research Ethics Committee \(SAHS/FUHREC\)](#). Potential participants are offered an information sheet which provides details of the study and invited to discuss the study with their doctor, study nurse and family prior to consenting to participate.

MS trials currently recruiting at Flinders;

COPERNICUS A Prospective, Parallel Group, Non-Randomised Open-Label Observational Study Comparing Copaxone® With Interferons In Patients With Confirmed Multiple Sclerosis.

This is an observational study which means that your doctor will follow current medical practice to treat you with medication that is available by prescription. There will be no changes to the way your doctor would normally treat you.

Purpose: MS has a significant impact on fatigue (tiredness), quality of life and cognition (thinking ability). The purpose of this study is to gain a better understanding of the long term benefits of four (4) current treatment choices available in Australia for MS and their relationship to participants fatigue, quality of life and cognition. These treatments are called Betaferon® (interferon-β1b), Rebif® (interferon-β1a), Avonex® (interferon-β1a), and Copaxone® (glatiramer acetate). To be able to enter the study, you may be taking one of these medications, or you may not be currently on any treatment for your MS or about to commence one of the above treatments.

The trial consists of 1 visit every 6 months for 2 years (5 visits in total). At these visits you will undergo a physical, medical history, questionnaires and audio tests (visit 1, 3, and 5).

Recruitment for this study ceases in February 2011.

TOWER A multi-centre double-blind parallel-group placebo-controlled study of the efficacy and safety of teriflunomide in patients with relapsing multiple sclerosis. Protocol: EFC10531

Purpose: The purpose of this study is to evaluate the effectiveness and safety of teriflunomide at the doses of 7 and 14 mg once daily compared to placebo (substance which contains no active medication) in the treatment of patients with MS.

Depending on when a person with MS joins the study, it will last anywhere from approximately 16 months to 3 years and 4 months. The exact duration will not be known until all of the patients enter the study. In order to monitor safety and determine if the study medication is effective, assessments will be required at regular intervals. Participant's will come to the study centre for blood tests for a minimum of at least 20 visits over approximately 16 months and 3 monthly for a physical examination and a pancreatic ultrasound.

Participants eligible to enter the study at randomisation, will be provided with 3 months of study drug (either teriflunomide or placebo) in which they will take one tablet per day.

Recruitment for this study ceases in September 2010.

TOPIC

An international, multi-centre, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of two year treatment with teriflunomide 7 mg once daily and 14 mg once daily versus placebo in patients with a first clinical episode suggestive of multiple sclerosis.

Purpose:

The purpose of this study is to examine the effectiveness and the potential risks of teriflunomide at the doses of 7 and 14 mg once daily compared to placebo (substance which contains no active medication) in the treatment of patients presenting with *their first neurological episode consistent with multiple sclerosis* (MS) and who have abnormalities on a brain Magnetic Resonance Image (MRI) that shows a risk of developing MS.

The total amount of time participants will be asked to participate in this study will be approximately 128 weeks (about 31 months including the screening and follow-up periods). In order to check safety and decide if the study medication is effective, assessments will be required at regular intervals. This will involve regular blood tests on at least 30 visits during the 128 weeks of the study as well as intermittent MRI's, physical examinations and ultrasounds.

Recruitment for this study ceases in 2011.

For further details on any of the above studies being conducted by Dr. Slee at Flinders Medical Centre please contact;

Dr. Mark Slee on 8204 4187

Or Marie Toubia (Research Coordinator) on 8204 4971