

Consent Form

Title of Study: Influence of Female Menstrual Cycle on Disease Activity in Multiple Sclerosis

Principle Investigator: _____

Coinvestigaor: _____

Description of Research by Investigators:

1. Purpose of the Study:

This study is designed to evaluate disease activity in patients with multiple sclerosis as it relates to female menstrual cycle. This protocol is designed to implement a study. The study will allow us to make correlations and draw conclusions about hormonal influences on the disease process. It will help us differentiate symptoms of Premenstrual Syndrome from symptoms of multiple sclerosis exacerbations. It will let us assess disease activity at different times during the menstrual cycle via MRI scan(s). It may also become a basis for a large long-term follow-up study.

2. Description:

If you voluntarily consent to participate in this study, you will receive a questionnaire with a temperature chart, on which you will be recording your symptoms and your daily temperature for a period of three months. It is crucial that you do not miss days in your reporting of the symptoms and temperature. However, if you forget to record your symptoms/temperature, you will need to resume your recording at the box corresponding to appropriate day of your cycle. More detailed instructions will be provided with the questionnaire. Your data will be compared to age-matched controls. The questionnaire will allow us to assess whether you do or do not consistently experience subjective worsening of your condition at specific times of your cycle. It will also help us distinguish your symptoms from those of Premenstrual Syndrome. The temperature chart is necessary to assess your ovarian function. After a period of three months the data will be collected and analyzed. Several patients will be selected for one or more follow-up neurologic examinations to record objective changes in their disease process. It will be provided free of charge. At a later date you may be asked ot undergo several blood tests and one or more brain MRI scans that will also be provided free of charge.

3. Procedures:

In order to be eligible for the study, you must be a female patient with established diagnosis of multiple sclerosis, between ages of 18 and 55. The study will require your full participation, and we will want precise documentation of your daily symptoms and temperature. We will need your complete medical history and you may be asked to undergo a neurological examination, blood tests and brain MRI scan(s). You may not participate in the study if you are premenarchal or postmenopausal, 8if you are currently pregnant, if you have a serious gynecologic condition for which you are being treated by a gynecologist, or if you have had a total hysterectomy. You are eligible to participate if you have had a hysterectomy, but your ovary(ies) were not removed.

4. Potential risks:

There are no risks associated with answering the questionnaire and filling out the temperature charts. The possible risks of drawing blood from a vein are bleeding, infection and slight bruising. These risks are excessively small and can be further minimized by using clean and careful techniques. There are no known risks associated with MRI testing for normal subjects. You cannot have an MRI scan if you are pregnant or if you have metal in your body. Patients with pacemakers cannot have an MRI scan.

5. Potential Benefits:

The community of patients and physicians will gain a better understanding of female hormones' influence on MS. We hope that the results of this study will help us distinguish between PMS symptoms and true MS exacerbations, and shed some light on the potential importance of estrogens in MS. You may receive one or more brain MRI scans and the cost of these scans will be covered by the study.

6. Therapy for multiple sclerosis:

This study will not alter or interfere with your current therapy for multiple sclerosis. In the event that you experience an attack of MS, any other unusual or unexpected symptom, you will contact your neurologist. For questions about this study you may contact: _____

7. Costs:

The laboratory costs, costs of MRI scans and neurological examinations will be paid by a sponsor.

8. Right to Refuse or Withdraw:

Participation in this study is entirely voluntary. You can withdraw your consent and discontinue your participation at any time without jeopardy to your future medical care. You must notify the investigator of your decision to withdraw.

9. Right of Investigator to withdraw the subject:

Investigators reserve the right to withdraw the subject from the study at any time.

10. Confidentiality:

All records will be maintained in confidence. However, all records will be reviewed by investigators. You will not be identified by name in any published report.

11. Institutional Review Board:

Place contact information here and any special IRB information.

12. Voluntary participation:

Participation in this study is entirely voluntary, and refusal to participate will not involve penalty or loss of benefits to which you are otherwise entitled. You may discontinue your participation at any time without loss of benefits of your regular medical care.

13. Unforeseeable risks:

We do not anticipate any risks that would result from participation in this study.

14. Number of subjects:

Approximately 30 subjects will be involved in the study.

15. New information:

If new information becomes available during the study which you may relate to your willingness to participate in the study, this information will be provided to you.

16. Institution's Liability Statement:

17. Consent:

I have received a copy of the consent form. I have read and understood the statements in the consent form. I voluntarily agree to participate in the study.

Name (print) _____ *Date* _____

Name (sign) _____

Witness _____ *Date* _____