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VERISMO

IRB Approved at the
Protocol Level
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Help us learn more about the health of people with multiple sclerosis (MS).

If you have MS and just started treatment with OCREVUS® (ocrelizumab) or another treatment for MS you may be able to join an observational research study.

Patient Study Guide

This Study Guide contains important information about the VERISMO Study. Please keep it in a safe place.

Welcome to the VERISMO Study!

Thank you for deciding to take part in this important observational research study. Your participation will last over a period of at least 5 years.

This Study Guide will help you understand what you can expect during the VERISMO Study. You may wish to bring it with you to your regular appointments with your neurologist.

If you have any questions, please ask a member of the study team. Contact details can be found on the back page of this Study Guide.

About the VERISMO Study

The VERISMO Study is an observational study. It will look at the safety of OCREVUS® (ocrelizumab), and at how well ocrelizumab is tolerated by patients to whom it is prescribed in routine practice. The study will look specifically at the occurrence of breast cancer and other types of cancer, and at the number and kind of side effects that may occur.

The outcomes in people who are taking ocrelizumab will be compared with people who are treated with other medications for MS.

What is an observational study?

The purpose of an observational study (a type of medical research study) is to learn more about approved medications and how they are used. For people who participate in these types of research studies, the treatment and medical care they receive are the same as people who do not participate. The information gathered during observational studies can help give doctors more information about treatments for medical conditions and how best to use them.

You and your doctor will be sharing information with the VERISMO Study Team based on your routine doctor appointments and other information you provide. Your personal information, such as your age and date of birth, together with any health information collected about you during the study, will be kept private.

Why is the VERISMO Study important?

Sometimes the effect that certain medications, such as ocrelizumab, have on people can only be seen when a large group of patients is studied. We can only investigate if a medication has any long-term effects when the patients who are exposed to this medication are observed for a number of years, such as in an observational study like this one.

Ocrelizumab is an approved treatment for both relapsing multiple sclerosis (MS) and primary progressive multiple sclerosis. It has been studied in several clinical research studies. However, there are many factors that can only be studied in everyday medical practice with many patients being followed.

Comparator group

The VERISMO Study will compare the outcomes in people who are taking ocrelizumab with people who are treated with other medications for MS. The medications for MS being studied are called disease-modifying therapies (or DMTs). DMTs aim to reduce the number and severity of relapses in people with MS. They can also slow down the damage caused by MS that builds up over time.

The study will follow 1000 patients who are taking ocrelizumab and 860 patients who are taking other DMTs.

What will happen during the VERISMO Study?

You will be in the VERISMO Study for at least 5 years. During the study, the investigator will collect information about you in your medical records.

The information collected at the start of the study (within 30 days of you starting your treatment with ocrelizumab or another DMT)

- Your age (year of birth), sex, height, and weight.
- Blood test results (if available).
- Information about your previous and current treatment for MS (name of treatment, dose, and the start/stop dates).
- Your medical history, including other diseases you may have or have had, and any medications you are taking or have taken within the last 3 months.
- Information about any side effects you have (or have had).
- If you are pregnant or not (only if you are a woman able to have children).
- Your alcohol consumption, tobacco smoking habits, and drug use.
- Contact information for your healthcare providers.

What will happen during the VERISMO Study? (continued)

Information collected during the study period

During the study, your doctor will decide on how your MS is treated, what tests or examinations are to be performed per routine medical care, and how often you visit the study center.

The results from these doctor visits, which are part of routine medical practice and are recorded in your medical records, may be collected for this study, if available:

- Updated weight
- Blood test results (if available)
- Information on your MS
- Information on your MS treatment(s), including
  - name of the treatment(s)
  - when you take it
  - your dose and any changes to your dose
  - if and when you stop taking (and/or restart) a treatment
  - and the reason(s) for stopping a treatment.

- Information on any other medications you might be taking.
- Data on any side effects, diseases, accidents, injuries, and other conditions that may affect your health during and after your treatment.
- If you are pregnant or not (only if you are a woman able to have children).
- Reasons for discontinuing the study, if you stop the study early.
- Next of kin contact information. Data is collected in case we cannot find you. This information will remain at the study center and will not be shared but with the site staff.

Note the following:

- If you are diagnosed with a malignancy (cancer), your medical records relating to the diagnosis of cancer will be sent to independent oncologists or pathologists to review and confirm the diagnosis.

What are my responsibilities during the study?

There are some important things to remember while taking part in the VERISMO Study.

- It is important that you tell the study doctor immediately about any side effects or changes in your health, whether or not you think they are related to your MS DMTs.
- Tell the study doctor about all medications you are currently taking and any changes to these medications.
- It is very important for this study that you tell the study doctor about the unlikely event that you would be diagnosed with cancer. The study doctor will collect the information about the diagnosis and any follow-up information from the doctor treating you for your cancer (if applicable).
- Please tell the study doctor if you no longer wish to participate in the study.

A few things to remember

✓ Taking part in this study is voluntary. You can stop taking part in the study at any time.

✓ Please contact a member of the study team as soon as possible if you:

- are thinking about leaving the study
- are diagnosed with cancer
- experience a life-threatening event, are hospitalized or need surgery

Contact information

If you have any questions during the study, please contact the study team.