MC18C2, Treatment of Established Chemotherapy-induced Neuropathy with Fingolimod: A Pilot Trial

NCT03943498

Date: 3/10/2021

MAYO CLINIC

Name and Clinic Number

Approval Date: **March 10, 2021**
Not to be used after: **March 9, 2022**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC18C2, Treatment of established chemotherapy-induced neuropathy with fingolimod:

IRB#: 19-001371

Principal Investigator: Dr. Loprinzi and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to determine if the use of this medication can reduce neuropathy. You have been asked to take to take part in this research because you developed neuropathy (weakness, numbness and pain in your hands and feet) due to your recent cancer treatment.
What's Involved	Study participation involves • Medical history, Physical examination • Review of your current and past medications • EKG • Pregnancy test if you are a woman of childbearing potential

	During the study: • You will start taking fingolimod by mouth daily for 4 weeks. • The initial dose of fingolimod will be started in the clinic with outpatient monitoring. Your heart rate and blood pressure will be checked every hour for 4 hours and then every 30 minutes for the next two hours. A repeat EKG will also be performed. • You will be completing patient questionnaires every week. You will be asked to complete a daily questionnaire about your symptoms you have experienced in the last 24 hours. The questionnaire should take less than 10 minutes to complete each day. Following completion of your treatment you will be asked to fill out questionnaires monthly for 3 months.
Key Information	Common risks include headache, diarrhea, nausea, abdominal pain, increased liver enzyme levels, infections, back pain, cough and low heart rate.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Charles Loprinzi, M.D. **Phone:** (507) 284-2511 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you developed neuropathy (for example, tingling, numbness, and pain in your hands and feet) due to your recent cancer treatment.

About 10 people will take part in this research study. The plan is to have about 5 people take part in this study at Mayo Clinic.

Why is this research study being done?

This study will use the study drug fingolimod, an FDA approved drug for treatment of multiple sclerosis. Fingolimod acts by suppressing immune reactions in the brain. It has never been studied in patients with cancer. Therefore, the possibility of fingolimod promoting tumor growth in patients with cancer cannot be ruled out. It is not currently FDA approved for the treatment of neuropathy. However there have been some studies to suggest fingolimod may help reduce neuropathy.

The purpose of this study is to determine if the use of this medication can reduce neuropathy caused by chemotherapy.

Information you should know

Who is Funding the Study?
Alliance and Breast Cancer Research Foundation are funding the study. They will pay Mayo Clinic to cover costs related to running the study.

How long will you be in this research study?

You will be in the study for 4 months.

What will happen to you while you are in this research study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra tests that you will need to have if you take part in this study.

Before you begin the study:
You will need to have the following tests to find out if you can be in the study:

- Review of your medical history
- Physical examination including height, weight, performance status evaluation (ability to perform daily functions)
- Review of your current and past medications
- EKG
- Pregnancy test if you are a woman of childbearing potential
- Blood tests

During the study:

- You will start taking fingolimod by mouth daily for 4 weeks.
- The initial dose of fingolimod will be started in the clinic with outpatient monitoring. Your heart rate and blood pressure will be checked every hour for 4 hours and then every 30 minutes for the next two hours. A repeat EKG will also be performed.
- You will be completing patient questionnaires every week .You will be asked to complete a daily questionnaire about your symptoms you have experienced in the last 24 hours. The questionnaire should take less than 10 minutes to complete each day.

Following completion of your treatment you will be asked to fill out-questionnaires monthly for 3 months.

You will be contacted by phone to remind you to fill these out and check in on you.

What are the possible risks or discomforts from being in this research study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to Fingolimod include those which are:

Common:

- Headache
- Diarrhea, nausea, abdominal pain
- Increased liver enzyme levels
- Infections
- Back pain
- Cough, sinusitis
- Low heart rate

Less common:

- High blood pressure
- Heart conditions
- Seizure
- Migraine
- Hair loss
- Scaly or crusty skin
- Fungal infection
- Change in cholesterol
- Increased in white blood cell count
- Decrease in number of white blood cells
- Skin tags
- Skin cancer
- Virus infection

- Pain
- Lack of energy
- Blurred vision
- Breathing difficulties

Rare:

- Swelling
- Heart problems
- Bacterial/fungal infection
- Stroke
- Liver problems
- Digestive system diseases
- Herpes simplex
- Hypersensitivity reaction,
- Viral infection that can be carried to the brain
- Secondary cancer
- Eye problems
- Multi-organ failure,
- Narrowing of the arteries
- Pneumonia
- Skin rash
- Decreased in blood pressure
- Hives

As with any medication, allergic reactions are a possibility.

Reproductive risks: You should not become pregnant or father a baby while on this study, because the drug used in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while taking the study medication and for two months after your last dose. Check with your health care provider about what kind of birth control methods to use and how long to use them.

Pregnancy and Birth Control:

1) Will women of child-bearing-potential be allowed to participate in this study?
   Yes: Women of child-bearing-potential will be able to participate in this study if they have a negative pregnancy test and agree to use acceptable birth control (see #5) since the risks to an unborn child are either unknown or potentially serious.

2) Will pregnant and/or nursing women be allowed to participate in this study?
No: We know that there are risks to a breast-fed infant or to an unborn child carried by a woman who takes part in this study if they receive the study drug fingolimod. Breast-feeding mothers must stop breast-feeding to take part in this study.
3) Do you need to have a pregnancy test done to be part of the study?
Yes: A pregnancy test will be done as part of your normal clinical care if you are a female of child-bearing potential.
4) Will men who are able to father a child be allowed to participate in this study?
Yes: Men who are able to father a child will be able to participate in this study if they agree to use acceptable birth control (see #5) since the risks to an unborn child are either unknown or potentially serious.
5) What types of birth control are acceptable?
Surgical sterilization
Approved hormonal contraceptives (such as birth control pills, Depo-Provera)
Barrier methods (such as a condom or diaphragm) used with a spermicide
An intrauterine device (IUD)
Abstinence

For your safety during this study, call the Principal Investigator BEFORE you take any:

- New medications prescribed by your doctor
- Other medications sold over-the-counter without a prescription
- Dietary or herbal supplements

Discomfort with Answering Questionnaires:
Some questions you will be asked to answer in the study questionnaires may make you feel uncomfortable. You may choose not to answer any questions that make you feel uncomfortable.

Are there reasons you might leave this research study early?

Taking part in this research study is voluntary. You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best clinical interest,
- if you do not follow the study procedures,

- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. The study will not offer free medical care or payment for any bad side effects from taking part in this study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

What are the possible benefits from being in this research study?

This study may not make your health better. However, you may find relief in neuropathy symptoms.

What alternative do you have if you choose not to participate in this research study?

You do not have to be in this study to receive treatment for your condition. Your other choices may include:

- Taking part in another study
- Getting treatment or care for your neuropathy without being in a study
- Getting no treatment

You should talk to the researcher and your regular physician about each of your choices before you decide if you will take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

The study drug Fingolimod will be given to you at no cost and the antibody test for varicella zoster virus; however, you may need to pay for the administration of the study drug. You and/or your insurance might also have to pay for other drugs or treatments given to help control side effects.

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Initial EKG testing at the beginning of the study and after the first dose.
- Cost of the fingolimod medication

You and/or your insurance will need to pay for all tests and procedures that are part of this research study. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. You will have to pay for any costs not covered by your insurance.

If you have questions about any costs to you that may result from taking part in the research, please speak with the Principal Investigator. If you wish, arrangements can be made for you to speak with someone in Patient Financial Services about these costs.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will not be paid for taking part in this study.

How will your privacy and the confidentiality of your records be protected?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature