



Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

A Pilot Study of Interrogating B-cell Signaling Pathways and in vitro Screening to Personalize Therapies in BTK Inhibitor Resistant Mantle Cell Lymphoma (MCL) - the MCL-MATCH Trial

2019-1022

Subtitle: MCL-MATCH Trial

Study Chair: Michael Wang

Participant's Name

Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

Several types of mantle cell lymphoma (MCL) are difficult to treat due to specific genetic changes (mutations or alterations in the DNA/RNA expression in the cells) that make them not respond to a certain type of drug called a Bruton's tyrosine kinase (BTK) inhibitor.

The goal of this clinical research study is to use genetic testing to identify which drugs may be most effective in treating patients with MCL who have this type of genetic mutation.

This is an investigational study.

This is not a treatment study. You will receive treatments assigned by this study, but the treatments could be either standard of care or as a part of a separate treatment study. You will not receive any drug(s) directly as part of this study. However, the genetic testing may help predict what therapies may work for you. Future patients may benefit from what is learned on this study. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience side effects due to blood draws and/or biopsies.

You can read a list of potential side effects below in the Possible Risks section of this consent.

There is no limit to the amount of time you will be followed as part of this study.

There will be no cost to you for taking part in this research study.

You may choose to receive standard of care therapies or enroll in other clinical research studies without taking part in this study.

1. STUDY DETAILS

Up to 20 participants will be enrolled in this study. All will take part at MD Anderson.

If you agree to take part in this study, you will provide the following samples for genetic testing:

- Blood (about 1 tablespoon) – if you can become pregnant, part of this sample will also be used for a pregnancy test. To take part in this study, you must not be pregnant.
- Saliva
- Tissue left over from a previous procedure.
- A new biopsy: This may be a bone marrow biopsy or another involved tissue biopsy. To collect a bone marrow biopsy, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle. The process for collecting a tissue biopsy will depend on its location. The study doctor will tell you more about this procedure, including its risks.

Researchers will use these collected samples to test the disease's response to different types of lymphoma treatment. One type of testing being used in this study is called differential gene expression (a test studying how different genes in the DNA are "expressed," or turned on or off). It is being performed using a machine called the nanoString nCounter system. Researchers will also perform laboratory tests on your samples using several different drugs to try to find the best match to treat your particular lymphoma type. These tests will result in a "score" that will help the researchers decide what drug or drug combination may work best for you.

If you agree to take part in this study, you will also be required to take part in one other MD Anderson laboratory research study (LAB11-0342). You will sign a separate consent form for this study, which allows the collection of blood, saliva or any tissue samples at appropriate times for MCL research studies.

You will not receive treatment directly as part of this study. If you receive treatment, it will either be as part of your standard care or as part of your participation on another clinical research study. The study doctor will explain to you what options are available to you. In either case, you will receive additional information at the time you receive treatment about the cost of treatment and if the drug(s) you receive are FDA-approved or not.

If you begin receiving treatment based on the results of this research testing, researchers from this study will check your medical records at the beginning of every cycle of therapy for the first year, every 2 months for the second year, every 4 months for the third year, then every 6 months after that. From time to time, the study team may call you on the phone to check your health status. This call should take about 5-10 minutes.

If the disease does not respond to the therapy you receive after the first round of the study testing, you may have up to 5 additional rounds of testing. Before each round, if the disease appears to have gotten worse, you will have a repeat biopsy to understand the molecular changes in your MCL cells and based on this information, the research team will assign a new set of therapies. If you can become pregnant, you may also have blood drawn for a pregnancy test.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

The type of **genetic testing** being performed in this study will not provide you or your doctor information about diseases that are passed down in families. It will not tell the study researchers anything that will prevent you from getting health insurance, and it will not tell the study researchers anything about any diseases or conditions you may get in the future.

If you enroll in a clinical research study based on your test results from this study, you will receive a separate consent form explaining that study and the risks of the study treatment.

If you receive standard of care therapy, the doctor will explain the treatment and how the drug works and its risks.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: You should follow the appropriate methods of birth control for the treatment you are receiving. Talk to the doctor who is treating you about appropriate methods of birth control.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance

provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Michael Wang, at 713-792-2860) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.
5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.
6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.
7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.
8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research

Samples collected from you as part of this study will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Precision for Medicine
- Future sponsors or supporters and/or licensees of the study technology
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SIGNATURE OF PARTICIPANT

DATE

PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

SIGNATURE OF WITNESS TO THE VERBAL CONSENT

DATE

PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR)

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

PERSON OBTAINING CONSENT

DATE

PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

NAME OF TRANSLATOR

SIGNATURE OF TRANSLATOR

DATE

Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)