Official Title:	A pilot study of subcutaneous mosunetuzumab with or without polatuzumab vedotin and obinutuzumab for untreated indolent B-cell non-Hodgkin lymphoma
NCT Number:	NCT05169658
Document Type:	Informed Consent Form
Date of the Document:	8/28/2024

Fred Hutchinson Cancer Center
University of Washington

Consent to take part in a research study:

A pilot study of subcutaneous mosunetuzumab with or without polatuzumab vedotin and obinutuzumab for untreated indolent B-cell non-Hodgkin lymphoma

RG1121407

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Important things to know about this study:

You are invited to participate in a research study. The purpose of this research is to determine whether or not mosunetuzumab with or without polatuzumab vedotin and obinutuzumab is an effective treatment for non-Hodgkin lymphoma.

People who agree to join the study may be followed for up to 5 years. The study involves physical examinations, blood draws, study drug IV infusions, and PET and CT scans, among other procedures.

We do not know if mosunetuzumab with or without polatuzumab vedotin and obinutuzumab would help treat non-Hodgkin lymphoma, and it could even make your condition/disease worse. Mosunetuzumab with or without polatuzumab vedotin and obinutuzumab could cause side effects such as neutropenia, cytokine release syndrome (CRS), anemia, increased risk of infections, and others as described below in this form.

If you decide to participate in this study, there will be two parts: Part A is the portion of the study where you will receive only mosunetuzumab. If you have progressive disease later on you may continue to Part B, which is the part where you will receive polatuzumab vedotin and obinutuzumab.

You do not have to join this study. You can choose to receive standard methods to treat your non-Hodgkin lymphoma instead of participating in this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study.

We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We invite you to join this research study.

We invite you to join this research study because you have non-Hodgkin lymphoma. Up to 42 people will join this study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

You do not have to be in the study. You are free to say "yes" or "no", or to drop out after joining. If you say "no," you would have no penalty or loss of benefits. Whatever you decide, your regular medical care would not change.

Why are we doing this study?

We are doing this study to examine the effects (both good and bad) of mosunetuzumab with or without polatuzumab vedotin and obinutuzumab on non-Hodgkin lymphoma. We want to know if this drug combination is effective at treating non-Hodgkin lymphoma without the need for conventional chemotherapy.

There are two parts to this study: Part A and Part B. The purpose of Part A is to evaluate how you respond to mosunetuzumab when it is given subcutaneously (SC). If you do not achieve a complete response with this regimen, you may be able to participate in Part B of the study. The purpose of Part B is to evaluate how you respond to polatuzumab vedotin and obinutuzumab.

Mosunetuzumab is an antibody. Antibodies are large, Y-shaped proteins used by your body's immune system to identify and neutralize foreign objects such as bacteria, viruses, and tumor cells. Mosunetuzumab has been engineered to attach to two target cells: B cells, which include certain types of cancerous B cells (Like in follicular lymphoma and marginal zone lymphoma) and normal T cells. T cells are another component of the immune system that normally perform tasks such as killing virus-infected cells. Mosunetuzumab has been designed to direct T cells to kill cancer cells instead. Thus, mosunetuzumab may work by directing the body's immune system to kill cancerous B cells.

What research tests, procedures, and treatments are done in this study?

If you join this study, we would do these tests and procedures:

Medical history. You will be asked questions about your medical history. This includes ongoing medical conditions you have and drugs you are taking.

Physical examination. Physical exams will assess your overall health status and include measuring your vital signs. This includes temperature, heart rate, breathing rate, and blood pressure. Your weight and your height will also be recorded. You will also be asked how easily you perform daily activities.

Routine laboratory tests. Blood samples will be taken for routine tests. About 2-3 teaspoons of blood will be taken and your blood will be tested for levels of certain components to see if it is safe for you to receive treatment. Urine will be collected for analysis.

Pregnancy test. If you are a person who could become pregnant, you will have a pregnancy test. A blood or urine sample will be taken for this test.

Tumor imaging.

- Computed tomography (CT) scan. CT is a medical X-ray imaging method. It provides 3-dimensional pictures of the body and organs by sections. CT scans of the chest, abdomen, pelvis, and neck will be done if there is known/suspected radiographically measurable disease.
- Positron emission tomography (PET) scan. PET is another imaging technique. It produces a 3-dimensional picture of processes going on at the cellular level in the body. A whole-body PET may be done if there is known/suspected radiographically measurable disease.

Bone marrow biopsy and aspirate. Bone marrow aspiration and biopsy may be done to see if your cancer has spread to the bone marrow. For the bone marrow aspirate, a sample of bone marrow cells is taken by a needle inserted into a bone in your body. For biopsy, a small piece of bone is removed. These tests are done under local anesthesia.

Research laboratory tests. 1-2 teaspoons of blood will be taken for research tests. The results will not be reported in your medical record.

Treatment administration. Mosunetuzumab will be given subcutaneously (SC), meaning beneath the skin.

If you participate in Part B, we will perform these tests and procedures:

- **Physical examination.** Physical exams will assess your overall health status and include measuring your vital signs. This includes temperature, heart rate, breathing rate, and blood pressure. Your weight and your height will also be recorded. You will also be asked how easily you perform daily activities.
- **Routine laboratory tests.** Blood samples will be taken for routine tests. About 2-3 teaspoons of blood will be taken and your blood will be tested for levels of certain components to see if it is safe for you to receive treatment. Urine will be collected for analysis.

- **Tumor imaging.**
  - Computed tomography (CT) scan. CT is a medical X-ray imaging method. It provides 3-dimensional pictures of the body and organs by sections. CT scans of the chest, abdomen, pelvis, and neck will be done if there is known/suspected radiographically measurable disease.
  - Positron emission tomography (PET) scan. PET is another imaging technique. It produces a 3-dimensional picture of processes going on at the cellular level in the body. A whole-body PET may be done if there is known/suspected radiographically measurable disease.
- **Bone marrow biopsy and aspirate**. Bone marrow aspiration and biopsy may be done to see if your cancer has spread to the bone marrow. For the bone marrow aspirate, a sample of bone marrow cells is taken by a needle inserted into a bone in your body. For biopsy, a small piece of bone is removed. These tests are done under local anesthesia.
- **Research laboratory tests.** 1-2 teaspoons of blood will be taken for research tests. The results will not be reported in your medical record.
- **Treatment administration.** Polatuzumab vedotin and obinutuzumab will be given through an intravenous (IV) infusion.

After you have finished taking mosunetuzumab with or without polatuzumab vedotin and obinutuzumab, you would enter the **follow-up** part of the study. We would do these tests and procedures:

Medical history. You will be asked questions about your medical history. This includes ongoing medical conditions you have and drugs you are taking.

We will also conduct genetic testing on your tissue and/or blood. Your blood and tissue contain DNA from both normal cells and in certain cases cancer cells. DNA makes up the genes that serve as the "instruction book" for the cells in our bodies. By studying genes, researchers can learn more about diseases such as cancer. There are many different types of genetic tests. The testing on your tissue samples might include genetic testing called whole genome sequencing. Whole genome sequencing looks at all the genetic information in your cells.

How long would you stay in this study?

If you join this study, you will stay in this study for about 5 years.

You would receive mosunetuzumab with or without polatuzumab vedotin and obinutuzumab for up to 24-42 weeks (6-10 months). After that, you would have regular follow-up exams in the office or clinic for 5 years.

Doctors could take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.

- You are not able or willing to follow study procedures.
- The whole study is stopped.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

If you decide to drop out, we would want you to tell the study doctor. The doctor could tell you about the effects of stopping the study drugs. You and the doctor could talk about the follow-up care and testing that would help the most. Before you leave the study, the doctor might ask you to continue in the off-study visit so that we can accurately assess your health status after completing the off-study visit.

Long-term follow-up means keeping track of someone's medical condition for a long time. If you join this study, we would call you to see how you are doing for up to 5 years after your final dose of study drug. We would also ask your doctor to send a copy of your medical records. This information will help us learn about the long-term effects of mosunetuzumab with or without polatuzumab vedotin and obinutuzumab.

You do not have to be in long-term follow-up. You could say "yes" or "no". Either way, you could still join this study. If you drop out of the study, you would be asked if we could call you to see how you are doing.

If you choose not to join long-term follow-up, you would not be contacted regularly, and we would not ask your doctor to send medical records, but we might still need to contact you for some other reason.

Study Calendar for Part A

Treatment Cycle/Title	Screening Period	Part A					End of Treatment[9]	Off study visit	**Long term follow up[10]**
		Cycle 1 Day 1	Cycle 1 Day 2	Cycle 1 Day 8	Cycle 1 Day 15	Cycles 2-8 Day 1			
Scheduling Timing and Window	-42 to -1d			± 1 day	± 1 day	± 2 days	± 2 days	4-6 weeks after Cycle 8 day 1	
Informed Consent	X								
Inclusion/Exclusion Criteria	X								
Medical History	X								
Prior and Concomitant Medication Review	X	X		X	X	X	X	X	
Trial Treatment Administration		X		X	X	X			
Post-study disease status									X
Survival Status									X
Review Adverse Events[2]	X	X		X	X	X	X	X	
Physical Examination	X	X		X	X	X	X	X	
Vital Signs and Weight	X	X		X	X	X	X	X	
Height	X								
ECOG Performance Status	X	X		X	X	X	X	X	
Pregnancy Test – Urine or Serum beta-HCG[1]	X								
PT/INR and aPTT	X								
CBC with Differential[8]	X	X		X	X	X[11]	X	X	
Comprehensive Serum Chemistry Panel[8] and LDH	X	X	X[11]	X	X	X	X	X	
Uric acid, Phosphate		X	X[11]						
HepB S Ag, Core Ab, Hep C and HIV screen	X								

Treatment Cycle/Title	Screening Period	Part A					End of Treatment[9]	Off study visit	**Long term follow up[10]**
		Cycle 1 Day 1	Cycle 1 Day 2	Cycle 1 Day 8	Cycle 1 Day 15	Cycles 2-8 Day 1			
Scheduling Timing and Window	-42 to -1d			± 1 day	± 1 day	± 2 days	± 2 days	4-6 weeks after Cycle 8 day 1	
Tumor Imaging[3]	X					X[3]	X[3]		
Bone Marrow Biopsy and Aspirate[4]	X						X		
Other Procedures (Optional)[5]	X								
Archival Tissue Collection, if Feasible[6]	X								
Correlative Studies Blood Collection[7]	X	X					X		

Cycle length = 21 days.

Study Calendar for Part B

Treatment Cycle/Title	Part B					Off study visit	Long term follow up[6]
	Cycle 9 Day 1	Cycle 9 Day 2	Cycle 9 Day 8	Cycle 9 Day 15	Cycles 10-14 Day 1		
Scheduling Timing and Window			± 1 day	± 1 day	± 2 days	4-6 weeks after Cycle 14 day 1	
Prior and Concomitant Medication Review	X		X	X	X	X	
Trial Treatment Administration	X		X	X	X		
Post-study disease status							X
Survival Status							X
Review Adverse Events[1]	X		X	X	X	X	
Physical Examination	X		X	X	X	X	
Vital Signs and Weight	X		X	X	X	X	
Height							
ECOG Performance Status	X		X	X	X	X	
CBC with Differential[5]	X		X	X	X[11]	X	
Comprehensive Serum Chemistry Panel[5] and LDH	X	X[7]	X	X	X	X	
Uric acid, Phosphate	X	X[7]					
Tumor Imaging[2]					X[2]	X	
Bone Marrow Biopsy and Aspirate[3]						X	
Correlative Studies Blood Collection[4]	X					X	

Cycle length = 21 days

What are the side effects (risks)?

In this part of the consent form, we describe the side effects we expect from the tests and treatments in this study. Mosunetuzumab with or without polatuzumab vedotin and obinutuzumab could cause side effects we do not know about yet. We carefully watch everyone in the study for side effects.

If you join this study, we would tell you if we discover new side effects that could affect you.

This form lists side effects of *individual* drugs. Other side effects could occur when we use these drugs *together*.

Side effects may be mild or very serious. Medicines could be given to help lessen side effects. Many side effects go away soon after you stop taking the study drug. In some cases, side effects can last a long time or never go away. There also is a risk of death.

Risks of Mosunetuzumab

Known side effects

- Cytokine release syndrome/infusion reaction (caused by small proteins called cytokines that are released from your immune system during study drug infusion), including symptoms of headache, fevers, chills, shortness of breath, rapid heartbeat, changes in blood pressure, and/or muscle aches in the hours or days following your infusion of mosunetuzumab. There is a chance that high cytokine levels could lead to hospitalization, life-threatening circumstances, or even death even though this study has included specific measures to minimize the risk of excessive production of cytokines. Cytokine release syndrome may require management in acute/intensive care services and in rare cases the need for intubation (a procedure to place a tube into a person's windpipe) to help with breathing.
- Neutropenia (low numbers of neutrophils, a type of white blood cell) and febrile neutropenia (fever associated with a low number of neutrophils). A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and/or difficulty breathing.
- Tumor lysis syndrome (metabolic abnormalities caused by the rapid destruction of a large number of tumor cells). Tumor lysis syndrome may be mild (resulting in some minor changes in blood tests) to severe (resulting in kidney damage).
- Worsening of symptoms related to a new infection (like the flu) that you get while you are receiving mosunetuzumab.
- Increased risk of infection or flare-up of past infections (like hepatitis B or rare viral infection of the brain called progressive multifocal leukoencephalopathy, or PML).

- Tumor flare that can be associated with inflammation or pain at the tumor site. This may manifest as fluid accumulating in the lungs causing breathing difficulties. Tumor mass enlargement could also result in compromise of the airway, gastrointestinal tract, major organs, or blood vessels, depending on the tumor location. Tumor inflammation or tumor flare may require additional medical or surgical treatments (e.g., anti-inflammatory medicines, invasive procedure, management in acute/intensive care services including in rare cases tracheostomy (a surgical procedure to place a tube into a person's windpipe)).
- Injection site reactions following mosunetuzumab administration beneath the skin.
- Pneumonia, a severe inflammation of the lungs in which the alveoli (tiny air sacs) are filled with fluid. This may cause a decrease in the amount of oxygen that blood can absorb from air breathed into the lung. Pneumonia is usually caused by infection but may also be caused by radiation therapy, allergy, or irritation of lung tissue by inhaled substances. It may involve part or all of the lungs.
- Rash, an area of the skin that has changes in texture or color and may look inflamed or irritated. The skin may be red, warm, scaly, bumpy, dry, itchy, swollen, or painful. It may also crack or blister. A rash can occur in one area of the body or all over the body and may look very different depending on the cause.
- Urinary tract infections, a condition in which bacteria invade and grow in the urinary tract (the kidneys, ureters, bladder, and urethra). Most urinary tract infections occur in the bladder or urethra. Signs and symptoms may include pain or burning during urination, cloudy or bad-smelling urine, blood in the urine, feeling a need to urinate often or right away, pain in the back or lower abdomen, fever, chills, and fatigue.
- Pyrexia, raised body temperature or fever.
- Sepsis, a life-threatening complication of an infection. Chemicals are released in the bloodstream to fight an infection which triggers inflammation throughout the body.
- Tumor pain, pain which is caused in the body when a cancerous tumor grows.
- Hypophosphatemia, a condition where there are low level of phosphate in your blood.
- An increased level of alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) in your blood, which may indicate liver damage.
- Headache
- Thrombocytopenia (low numbers of platelets, a component of your blood). A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.

Rare potential side effects (<2% of patients)

- Neurological adverse events, including neurotoxicity (Immune effector cell-associated neurotoxicity syndrome, ICANS) or the tendency of some treatments to cause damage to the nervous system. Symptoms include tremor

(muscle contraction leading to shaking movements in one or more parts of the body), dysgraphia (a learning disability that affects writing abilities), expressive aphasia (a communication disorder that can make it difficult to produce speech), impaired attention, seizure, confusion, and apraxia (difficulty with skilled movements even when a person has the ability and desire to do them).

- Hemophagocytic lymphohistiocytosis (a severe uncontrolled inflammatory reaction with signs and symptoms that may be similar to those caused by cytokine release syndromeas described above)
- There is a chance that your immune system might develop special antibodies (proteins made in the body that respond to a substance that is foreign to the body) to this drug. If you develop these special antibodies, it may affect your body's ability to respond to mosunetuzumab in the future. Blood samples will be drawn to monitor for the development of these antibodies during study treatment and at your treatment discontinuation visit.
- Malabsorption (a condition that prevents absorption of nutrients through the small intestine. Symptoms include weight loss, bloating, and sometimes diarrhea. Eventually, the brain, nervous system, bones, liver, and other organs can be affected.)
- Eye pain, blurred vision, eye irritation, and light sensitivity could indicate uveitis, which is inflammation inside your eye

Risks of Polatuzumab vedotin

Known side effects

- Neutropenia (low numbers of neutrophils, a type of white blood cell), including fever with neutropenia
- Anemia (low red blood cell count)
- Thrombocytopenia (low platelet counts)
- Increased risk of infections (pneumonia, including fungal pneumonias, and other infections, including sepsis and viral infections such as shingles)
- Infusion-related or allergic reaction with symptoms such as fever, chills, low blood pressure, rash, headache, nausea, or vomiting
- Peripheral sensory and/or motor neuropathy (tingling, pain, numbness, sensation of pins and needles in arms and/or legs, weakness, and imbalance)
- Gastrointestinal disturbance (for example, vomiting, diarrhea, nausea, constipation, loss of appetite)
- Pancytopenia (low number of red blood cells, white blood cells, and platelets)
- Cellulitis (a common bacterial skin infection that causes redness, swelling, and pain in the infected area of the skin)
- Pneumocystis jirovecii pneumonia, a serious infection
- Urinary tract infection
- Fatigue and weakness

Potential side effects

- Side effects on reproduction and fertility (the ability to become pregnant)
- Hyperglycemia (high levels of blood sugar); if severe may require hospitalization and urgent treatment
- Progressive multifocal leukoencephalopathy or PML (a rare viral infection of the brain)
- Lung injury
- Hair loss
- Alteration of taste
- Eye disorders
- Changes in your liver, including abnormalities in liver function tests and/or changes in the appearance of the liver on imaging scans
- Reduction of renal function
- Joint pain/arthralgia/skeletal pain
- Changes to heart rhythm
- Tumor lysis syndrome (metabolic abnormalities caused by the rapid destruction of a large number of tumor cells). Tumor lysis syndrome may be mild (resulting in some minor changes in blood tests) to severe (resulting in kidney damage).
- Secondary malignancies (chance of development of another cancer)
- Immunogenicity (anti-drug antibodies, proteins made in the body that respond to a substance that is foreign to the body by your immune system, may be developed by your immune system)

Risks of Obinutuzumab

Likely (more than 10% of patients)

- Infusion-related reaction (reaction that can occur during or following infusion of the drug; may include fever, chills, rash, low blood pressure, and difficulty breathing)
- Neutropenia (decrease in neutrophils, a type of white blood cell that fights infections, see below)
- Anemia (decrease red blood cells)
- Constipation (difficulty passing stools)
- Asthenia (physical weakness, lack of energy)
- Arthralgia (pain in joints)
- Worsening of preexisting cardiac conditions
- Headache
- Infections
- Febrile neutropenia (fever associated with dangerously low levels of a type of white blood cell [neutrophils])
- Thrombocytopenia (decreased platelet count, cells that help stop bleeding; see below)
- Diarrhea (frequent, loose watery stools)
- Pyrexia (fever)

- Upper-respiratory tract infection (cold)
- Insomnia (difficulty sleeping)
- Alopecia (hair loss)
- Hepatitis B reactivation
- Herpes zoster (shingles)
- Prolonged B-cell depletion
- Sinusitis (sinus infection)
- Cough
- Nasopharyngitis (infection of the nose and throat)
- Urinary tract infection

Less likely (1%-10% of patients)

- Leukopenia, neutrophil count decrease, white blood cell count decreased (a decrease in number of a certain type of white blood cells)
- Oral herpes (an infection of the lips, mouth, or gums)
- Pharyngitis (sore throat), rhinitis, rhinorrhea (runny nose), nasal congestion (stuffy nose)
- Hyperuricemia (high level of uric acid in the blood)
- Musculoskeletal chest pain (pain in the muscles, joints or bones), bone pain, chest pain
- Atrial fibrillation (irregular heart rate)
- Lymph node pain
- Ocular hyperemia (red eye)
- Colitis (inflammation of large intestine)
- Influenza (flu)
- Fatigue (tiredness)
- Anxiety
- Sepsis (severe illness in which the bloodstream is overwhelmed by bacteria)
- Dysuria (trouble urinating), urinary incontinence (the loss of bladder control)
- Tumor lysis syndrome (metabolic abnormalities caused by the rapid destruction of a large number of tumor cells). Tumor lysis syndrome may be mild (resulting in some minor changes in blood tests) to severe (resulting in kidney damage).
- Hypertension (high blood pressure)
- Weight increased
- Squamous cell carcinoma of skin (common form of skin cancer)
- Cardiac failure
- Dyspepsia (indigestion)
- Hemorrhoids (An enlarged or swollen blood vessel, usually located near the anus or the rectum)
- Lung infection, including pneumonia
- Pruritus (itching), eczema (inflammation of the skin)
- Pain in extremity, back pain
- Depression
- Night sweats

- Hypokalemia (low blood potassium)

Rare but serious (unknown frequency)

- Progressive multifocal leukoencephalopathy, or PML (brain infection)
- Coagulation abnormalities including disseminated intravascular coagulation, or DIC (conditions that affect the blood's clotting activities)

Radiation risks

Some of the tests that you will have in this research study will expose you to radiation. Everyone receives a small amount of radiation every day called "background radiation". This radiation is natural and comes from space, air, water, soil, and the food you eat. Each year you are exposed to about 3 milliSieverts (mSv) of this background radiation. A milliSievert is a unit of radiation dose. There is minimal risk to your health from the amount of radiation you will receive in this study. The usual lifetime risk of getting cancer is 42%. For every 10 mSv you receive, your risk may increase 0.1%. If you have more procedures that expose you to radiation, your risk will go up. For comparison, the estimated radiation dose from each of these tests is listed below:

CT-chest: 7 mSv
CT-abdomen: 8 mSv
CT-pelvis: 6 mSv
CT-neck: 3 mSv
18-FDG PET/CT: 19 mSv

Reproductive risks

Chemotherapy and radiation treatments could cause sterility (unable to have children).

Taking mosunetuzumab with or without polatuzumab vedotin may involve unknown risks to an embryo, fetus (unborn baby) or nursing infant. Therefore, you could not join this study if you are pregnant, if you are planning to become pregnant, or if you are breast-feeding.

If you join this study, you would have to use an effective method of birth control from the time this form is signed until at least 12 months after the last dose of study treatment. If you are already using a method of birth control, you would have to check with the study doctor or a member of the study staff to make sure it is acceptable.

If you became pregnant after joining this study, you would have to notify the study doctor immediately. Participation in this study would end, and you would receive counseling and follow-up throughout the pregnancy and for about 6 months after the child is born.

The effects of mosunetuzumab with or without polatuzumab vedotin and obinutuzumab on fathering a child are also unknown. Men who join this study must also agree to use one or more forms of effective and acceptable birth control from the time this form is

signed until at least 5 months after the last dose of polatuzumab vedotin. Birth control methods required for men on this study include condoms.

Blood Draws

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or get an infection. Infection rarely happens. There may be redness and irritation at the place where the needle enters your vein.

Bone marrow aspiration and biopsy

The risks of this procedure include bleeding, infection, local nerve damage, pain from the needle sticks, and pain from aspirating the bone marrow with a syringe. Care will be taken to avoid these complications.

Non-physical risks

If you join this study, non-physical risks are:

- You might not be able to work.
- Results of genetic tests might be released by accident. This risk is very low, because we keep personal information private. If these results became known, you could have problems from others knowing about your genetic test results. For example, the results could cause stress or anxiety in family members who learn about their own risk of developing disease, or you could have problems with insurance because of your health status. There is also a risk that these test results could be combined with other information to identify you.

What are the benefits?

We do not know if mosunetuzumab with or without polatuzumab vedotin and obinutuzumab would help treat non-Hodgkin lymphoma. We hope the information from this study will help people with non-Hodgkin lymphoma in the future.

You have other choices besides this study.

You do not have to join this study. You are free to say “yes” or “no”. Your regular medical care would not change if you decide to say “no”.

You have other choices for treatment. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about these choices.

Other choices include: standard treatment, another research study, no treatment, or comfort care.

By enrolling in this study, you are forgoing treatment with approved agents with known clinical benefit. Your doctor will have a discussion with you that includes details of these treatments in comparison to treatment on this study.

Enrollment in this study may exclude you from other research studies.

Protecting Privacy as an Individual and the Confidentiality of Personal Information

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Genentech (the funder of this study and provider of mosunetuzumab, polatuzumab vedotin, and obinutuzumab) its parent company, Roche Holdings, Inc., and their affiliated entities, representatives, collaborators, and licensees.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center and University of Washington.
- Office for Human Research Protections, Food and Drug Administration, and other regulatory agencies as required.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

How is my genetic information protected?

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevents health insurance companies or group health plans from:

- Asking for genetic information obtained in research studies, or

- Using genetic information when making decisions regarding your eligibility or premiums

GINA *does not* help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

Would we pay you if you join this study?

There is no payment for being in this study.

Participants who travel 40 miles or more to the study site may be eligible for lodging for a single-night stay per study schedule time-point. This eligibility may be applied to visits from the time of the screening visit through the end of treatment visit (example, 1-night stay for the screening trip, 1-night stay for a cycle 1 trip, etc.). It does not extend to any visits that are considered to be "follow-up". The maximum reimbursement per visit is up to $140.

If you are eligible, please let the study team know if you require lodging as the study staff will make hotel arrangements on your behalf.

Would you have extra costs if you join this study?

If you join this study, you or your insurance company would have to pay for the costs of standard treatment in this study.

You would **not** be billed for:

- The cost of mosunetuzumab, polatuzumab vedotin, and obinutuzumab.
- Any research testing done on your tissue or blood solely for the purposes of this research study.

If mosunetuzumab with or without polatuzumab vedotin and obinutuzumab is approved as a treatment while this study is still going on, you or your insurance company might have to pay for the study treatment in order to complete this study.

What if you get sick or hurt after you join this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact your study doctor. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information and/or tissue samples be used for?

Your information and tissue samples (such as blood and tumor cells) will be used for the purposes of this study.

Your tissue samples might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.

During this study, if the researchers learn new information that could possibly be important to your general health or to you disease or condition, they will not be able to share that information with you because the tests are investigational.

Your information and tissue samples (even if made anonymous) will not be used for any research other than this study.

Future genetic research databases

Several genetic databases are available to help researchers understand different diseases. These databases contain DNA code and medical information from participants who have various diseases.

As part of this study, we would like to release DNA code and information about your medical condition into a genetic database in order to help future research. The genetic database would not contain names, addresses, or other information that could be used to identify you.

The DNA code in a genetic database cannot be used by itself to identify any specific person. A researcher who already has DNA code about you could use information from a genetic database to learn more about you. Once we release information to a genetic database, we no longer have any control over the use of this information.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.

- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

- If you decide to drop out, we would want you to tell the study doctor. The doctor could tell you about the effects of stopping mosunetuzumab with or without polatuzumab vedotin. You and the doctor could talk about the follow-up care and testing that would help the most.

- Before you leave the study, the doctor might ask you to continue in the long term follow-up part of the study.

  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.

Your responsibilities

If you join this study, you would have some responsibilities.

- Follow the schedule of study visits and procedures.
- Take study medications as directed.
- Prevent pregnancy.
- Tell us about side effects.

For more information

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	(206) 606-1739 (Dr. Ryan Lynch)
If you get sick or hurt in this study	(206) 606-1739 (Dr. Ryan Lynch)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	(206) 606-1377 (Patient Financial Services, Fred Hutchinson Cancer Center)

Emergency number (24 hours): (206) 598-6190

Read each question and think about your choice. When you decide on each question, please circle **YES** or **NO**.

Do you agree to have 2-4 teaspoons of blood collected at screening, at the beginning of every cycle, and at the end of treatment visit for research purposes?

(circle one)

YES **NO**

Do you agree to have genetic analyses performed on blood and/or tissue specimens for research purposes?

(circle one)

YES **NO**

Signatures

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant (age 18+):

Printed Name	Signature	Date

If you served as an interpreter or impartial witness during the consent process, sign below to indicate you attest to the accuracy of the presentation and the participant's apparent understanding of and willingness to participate in the research.

Impartial Witness or Interpreter:

Printed Name	Signature	Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol: RG1121407
Current consent version date: 08/13/2024
Previous consent version date: 05/31/2024
Copies to: Researcher's file
Subject
Subject's medical record