

Your guide to the SGN35-032 STUDY

A clinical research study for
people with peripheral T-cell
lymphoma (PTCL)



Important information about study participation

This guide must be provided to
you by your treating physician
or the study physician.

Welcome to the SGN35-032 STUDY

Thank you for your interest in the SGN35-032 Study for people with peripheral T-cell lymphoma (PTCL).

This guide will provide information about the study and review the tests and procedures you will have during your participation. Please read through the guide and refer to it as necessary throughout the study.

If you have questions at any point during the study, please speak with the study doctor.



The images depicted contain models and are being used for illustrative purposes only.

What is the SGN35-032 STUDY?

Peripheral T-cell lymphoma (PTCL) is a rare group of aggressive lymphomas that are a subtype of non-Hodgkin's lymphoma (NHL). PTCL develops from a type of mature white blood cells called T-cells.

The SGN35-032 Study, for men and women age 18 and older, is evaluating a study medicine (brentuximab vedotin) as a potential treatment for PTCL that has not been treated. In this clinical study, brentuximab vedotin is combined with a type of chemotherapy called CHP. The drugs in CHP are cyclophosphamide, doxorubicin and prednisone. All participants in the study will receive this combination treatment.

Brentuximab vedotin has been approved by the Food and Drug Administration (FDA) as a treatment in the United States for certain diseases. The drugs in CHP have been approved by the FDA in the United States for certain kinds of PTCL and other diseases.



An overview of the SGN35-032 Study

Participation in the study may last 2 years or more. The study is divided into the following periods:

- Screening period (up to 4 weeks):
 - You will have some tests and procedures to see if you can be in the study.
 - These tests will be done during 1 or 2 office visits.
- Treatment period (up to 6 months):
 - You will have visits to the clinic where you will get the study drugs in 21-day cycles for 6 to 8 cycles. These visits will last about 4 to 6 hours.
 - At the clinic, you will get brentuximab vedotin, cyclophosphamide and doxorubicin through a vein in your arm (intravenous, or IV) on Day 1 of each study cycle. You will get the drugs one at a time.
 - The study doctor will give you prednisone to take at home. You will take prednisone in pills by mouth at home on Day 1, Day 2, Day 3, Day 4 and Day 5 of each study cycle.
 - During clinic visits, you will also answer questions about your health, have your weight and height taken, and have blood tests.
 - You will have an extra clinic visit during Cycle 4 that will last about 2 to 6 hours. During this visit you may have CT scan, a PET scan and a bone marrow biopsy.

- End-of-treatment visit (30 days after last treatment):
 - During this visit, the study team will ask about how you are doing and about your cancer.
 - You will have some tests and a scan. You may also have an exam and a bone marrow biopsy.
- Long-term follow-up period (2 years or more):
 - You will continue to have follow-up visits at the clinic about every 3 months. After 2 years, you will visit the clinic about every 6 months.
 - At these clinic visits, you will have an exam and answer some questions about your health. You may also have a scan.
 - If your cancer gets worse, you won't have any more clinic visits. Instead, the study team will call you about every 6 months to see how you are doing and ask about your cancer.

Your participation in the study includes:

- The study drugs
- Study-specific visits, assessments and procedures

You may also be reimbursed for travel, lodging and meals associated with study visits.

You can decide to stop being in the study at any time. You can still go to your regular hospital or clinic for treatment after you leave this study.

Study Appointment Schedule

This calendar shows the days when you'll come to the clinic and about how much time you'll spend during your visit.

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
 <p>4-6 hours</p>						
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
 <p>Cycle 4 and the last cycle only; 2-6 hours</p>						

 = Biopsy

 = Blood samples

 = CT scan

 = Physical exam

 = Study drug infusion

Tests and Procedures

Below is a list of the tests and procedures you can expect during screening and the rest of the study. These tests and procedures allow the study doctor to closely monitor your health and safety throughout the study. Ask your study staff if you would like to know what tests and procedures will be done on a specific day.

- Questions about how you are feeling and your medical history. This will include asking about other medical problems, medications you are taking, allergies to medications, treatments you have gotten for your cancer, your activity level, and your general well-being.
- A physical exam. Physical exams include measuring your vital signs (blood pressure, heart rate and temperature) and measuring your height and weight. We will also look for signs and symptoms of cancer in your body.
- Blood samples 1 time during each study cycle for safety and research tests. The total amount taken during a visit will be between 1.5 and 4 teaspoons. Your body will make new blood to replace the blood that is taken for these tests.

If you have HIV, you'll have a blood test to check your CD4 count, which is the number of white blood cells. It will also check your viral load, which is the amount of HIV in your blood. You'll have this test during screening, about 3 weeks after you start taking the study drugs (Cycle 2) and every 12 weeks after that.

- CT and PET scans to look for signs of cancer. You will have CT and PET scans to look for signs of cancer during screening and about 3 months later (Cycle 4). You may have a CT scan and a PET scan after your last dose of study drugs. Ask your study doctor when you will have these scans.

- An electrocardiogram (ECG) and echocardiogram (ECHO). These are painless tests that measure the electrical activity and health of your heart.
- Bone marrow biopsy. This test will take a small piece of bone marrow from a bone in your body (such as your hip bone). You will get medicine to numb the area before the samples are taken. You will have a bone marrow biopsy before the first study visit. If your first bone marrow biopsy shows signs of cancer, you will have another bone marrow biopsy about 3 months later (Cycle 4). You may also have a bone marrow biopsy after you get your last dose of study drugs.
- Tumor biopsy. You will have a tumor biopsy during screening. This test takes a biopsy of your tumor by inserting a needle into your body and taking out a small piece of the tumor. You will get medicine to numb the area before the samples are taken. The study staff will use the sample from this test for research.
- Pregnancy test. You and your partner should not try to get pregnant while one of you is in this study. If you can become pregnant, you will have a pregnancy test at each treatment visit.
- Study drugs. You will get the following study drugs as an infusion through a vein in your arm:
 - Brentuximab vedotin
 - Cyclophosphamide
 - Doxorubicin

You will get prednisone in pills to take by mouth at home on Day 1, Day 2, Day 3, Day 4 and Day 5 of each 21-day cycle.

Questions During Your Participation in the **SGN35-032** **STUDY**

If you have any questions or concerns during the study, please contact your study doctor or the study team right away. You can also refer to the Informed Consent Form, which is your primary source of information throughout the study.



PTCLresearchstudy.com

From everyone at the
SGN35-032 Study, we
thank you for your time
and participation.