



Daiichi-Sankyo

Clinical Results Summary

A clinical study to learn more about the safety and effects of PLX3397 in people with returning or treatment-resistant Hodgkin lymphoma

Protocol number: PLX108-03

Thank You!



Daiichi Sankyo, Inc., the sponsor of this study, would like to thank the participants who took part in this study for PLX3397. Each participant helped to advance medical research for people affected with returning or treatment-resistant Hodgkin lymphoma. Their contribution to medicine and healthcare is greatly appreciated.

Important note: This summary only shows the results of a single study. Other studies may have different findings. Researchers and health authorities look at the results of many studies to understand which treatments work and how they work. It takes a lot of people in many studies around the world to advance medical science and healthcare.

Do not use the results of this study to make health decisions. Please talk to a doctor before changing any treatment you are taking or if you have any questions about these study results.

What was the main purpose of this study?

Hodgkin lymphoma

Hodgkin lymphoma is a type of cancer that starts in the lymphocytes. Lymphocytes are a type of white blood cells that are part of the immune system and help the body fight infections. The most common symptom of Hodgkin lymphoma is a painless swelling in a lymph node, usually in the neck, armpit, or groin area.

Currently, treatment options for Hodgkin lymphoma include chemotherapy, radiation therapy, and stem-cell transplantation. Chemotherapy is the use of anti-cancer medicine for cancer treatment. Radiation therapy is a type of cancer treatment that uses X-rays to kill cancer cells. Stem-cell transplantation is the process of replacing damaged stem cells with healthy stem cells from the bone marrow.

However, some people may have Hodgkin lymphoma that either does not respond to any of these treatments or comes back after being treated. Therefore, new methods for treating Hodgkin lymphoma are needed.

PLX3397 is a study treatment that is being tested for its ability to reduce the growth of cancer cells. In this study, researchers wanted to see if giving PLX3397 to participants with returning or treatment-resistant Hodgkin lymphoma can decrease the size of their tumor.

Treatment given in this study



PLX3397 (Study Treatment)

A treatment being studied for Hodgkin lymphoma. When the study started, PLX3397 was not approved for use. This means that it could only be used in a research study such as this one.

Main goal of this study

The main question the researchers wanted to answer in this study was:

 How many participants had tumors that became at least 50% smaller after PLX3397 treatment?

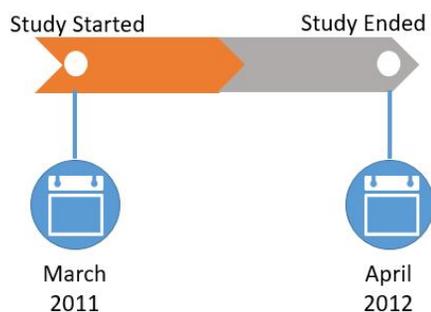
Other goals of this study

Other questions researchers wanted to answer in this study were:

- For participants whose tumor became at least 50% smaller, how long did the effect of PLX3397 treatment last?
- How long did participants live with their cancer before it got worse?

Researchers also closely monitored the health of the participants throughout the study.

How long was this study?



The study was designed in such a way that the participants could continue in it as long as their cancer did not get worse and they did not have serious side effects. The study started in March 2011 and ended in April 2012.

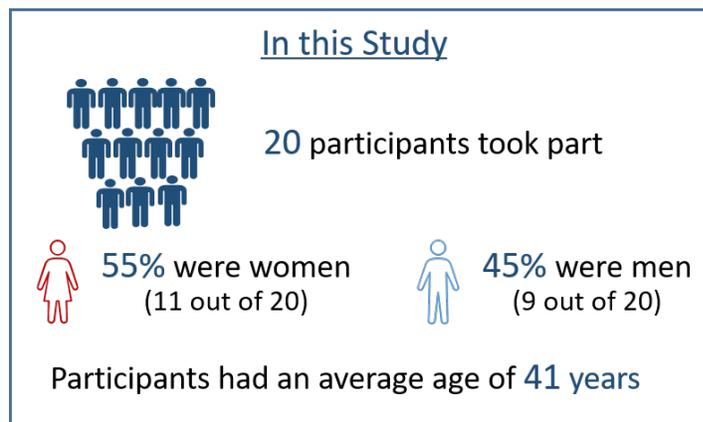
When the study ended, a report was created with the information that was available. This summary is based on that report.

Who was in this study?

This study included 20 participants from 6 centers in the United States.

Participants could take part in this study if they:

- were at least 18 years of age,
- had confirmed returning or treatment-resistant Hodgkin lymphoma with a tumor that could be measured,
- had normal blood, liver, and kidney function,
- had not received cancer treatment that lowered the body's immune system up to 3 months before the start of treatment, and
- had not received other cancer therapy up to 28 days before the start of treatment or had fully recovered from its side effects.



What happened during this study?

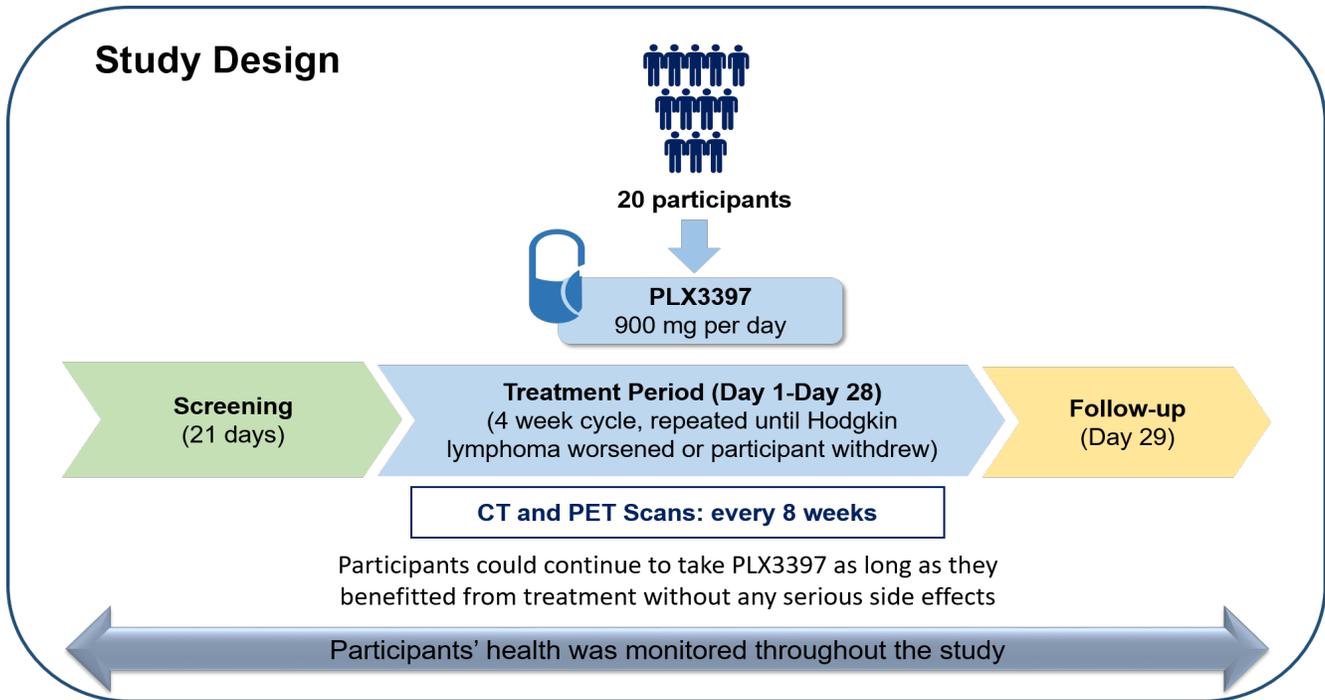
This was an open-label study, which means that both the researchers and the participants knew which treatment was given to which participant.

Participants completed a screening period to find out if they could be a part of the study. Eligible participants also had to provide a sample of tumor tissue at the time of screening and again after 15 days, if required.

All participants received 900 milligrams (mg) of the study treatment by mouth daily in cycles of 4 weeks. Participants could continue to take study treatment as long as they benefitted without any serious side effects.

The researchers used scans called computed tomography (CT) and positron emission tomography (PET) to measure the participants' tumor size at different times during the study. If their tumor had not increased in size, participants could continue to another cycle of treatment. The researchers also closely monitored the overall health of the participants throughout the study.

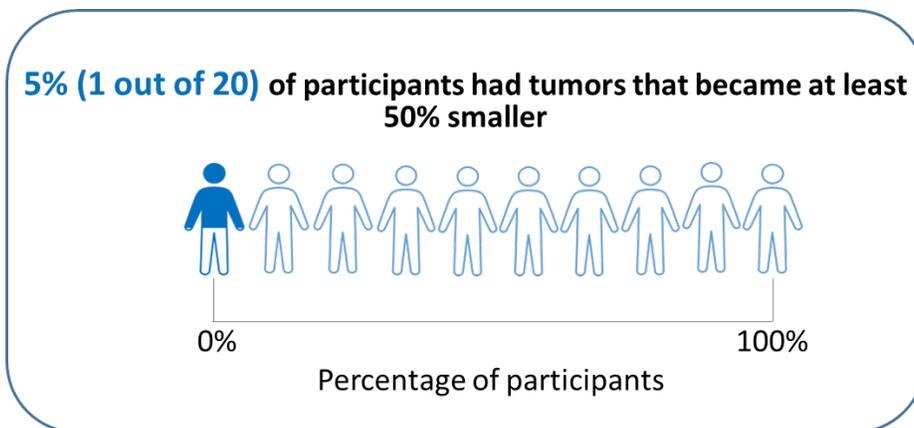
Study Design



What were the key results of this study?

Key results from this study are shown for the total group of participants as average results. This summary does not show the results from each individual participant. An individual participant's results could be different from the total group of participants. A full list of the questions the researchers wanted to answer and a detailed presentation of the results can be found on the website listed at the end of this summary.

How many participants had tumors that became at least 50% smaller after PLX3397 treatment?



What were the other results of this study?

For participants whose tumor became at least 50% smaller, how long did the effect of PLX3397 treatment last?

The participant who responded to PLX3397 treatment maintained the response for about [37 weeks](#).

How long did participants live with their cancer before it got worse?

About half the participants lived for at least [8 weeks](#) before their cancer got worse or led to death, whichever occurred first.

What medical problems did the study participants have?

Side effects are medical problems (such as feeling tired) that happened during the study, which the study doctor thought could be related to the treatment in the study. This section provides a summary of side effects related to the study treatment PLX3397. The website listed at the end of this summary has more information about the side effects that happened in this study.

Side effects are considered serious if they cause death, are life-threatening, cause lasting problems, or require hospitalization. Some participants stopped study treatment because of side effects.

How many participants had serious side effects?

1 participant (5%) reported 2 serious side effects of fever and infection in the lungs. There were no deaths related to study treatment.

What were the most common side effects?

The most common side effects, both serious and non-serious, that were reported by at least 10% of participants are presented below.

Side Effects	Percentage (Number of Participants)
Hair color change	 40% (8 out of 20)
Feeling very tired	 35% (7 out of 20)
Decrease in red blood cell count	 25% (5 out of 20)
Increase in levels of lactate dehydrogenase in the blood	 20% (4 out of 20)
Rash	 20% (4 out of 20)
Dizziness	 10% (2 out of 20)
Fever	 10% (2 out of 20)
Headache	 10% (2 out of 20)
Increase in liver test value of aspartate aminotransferase in the blood	 10% (2 out of 20)
Low blood platelet count	 10% (2 out of 20)
Low neutrophil count	 10% (2 out of 20)
Shortness of breath	 10% (2 out of 20)

Neutrophils are a type of white blood cell that help fight infections.
Platelets are tiny blood cells that help the body form blood clots to stop bleeding.

How was this study useful for patients and researchers?

This study helped researchers learn about how well PLX3397 is able to decrease tumor size in participants with returning or treatment-resistant Hodgkin lymphoma. Other studies of PLX3397 are ongoing.

Please remember, this summary only shows the results of a single study. Other studies may have different findings. Please talk to a doctor before changing any treatment you are taking or if you have any questions about these study results.

Where can I learn more about this study?

You can find more information about this study on the following website:

 www.clinicaltrials.gov Use the NCT identifier NCT01217229 in the search field.

Please remember that the results on this website may be presented in a different way. If you were a study participant and have questions about the results of this study, please speak with the doctor or staff at your study site.

Full study title: A phase 2 safety and efficacy study of orally administered PLX3397 in adults with relapsed or refractory Hodgkin lymphoma.

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