AstraZeneca

Clinical Study Results

Research Sponsor: Acerta Pharma BV

Drugs Studied:
- AZD9150
- AZD6738
- AZD5153
- Hu5F9-G4
- rituximab
- acalabrutinib

Study Purpose: This study was done to learn about the safety of 4 different combination treatments in adults with relapsed or refractory non-Hodgkin's lymphoma.

Protocol Number: D9820C00001

Thank you

Thank you for taking part in the clinical study for the study drugs AZD9150, AZD6738, AZD5153, Hu5F9-G4, rituximab, and acalabrutinib. This study investigated 4 different combinations of these treatments in people with non-Hodgkin's lymphoma.

Acerta Pharma BV sponsored this study and believes it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you.

If you participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

Who took part in this study?

The researchers asked for the help of men and women with non-Hodgkin's lymphoma. The participants in this study were 34 to 88 years old when they joined. The participants:

- had cancer that hadn't improved with earlier treatment **or** their cancer had come back again after treatment
- had tried more than 1 treatment for their cancer **and** no other treatment options were suitable for them
- could carry out some of their daily tasks
- had at least 1 swollen lymph node at least 15 millimeters in size

The study included 30 participants in the United States and the United Kingdom.

The study was split into 4 smaller treatment groups. Each group got a different combination of study drugs.

Why was the research needed?

Researchers are looking for a better way to treat people with non-Hodgkin's lymphoma. Before a drug can be approved for people to get, researchers do clinical studies to find out how safe it is and how it works.

Non-Hodgkin's lymphoma is a type of blood cancer that starts in a part of the immune system called the "lymphatic system". The lymphatic system is a part of the body's immune system that helps transport white blood cells, also called "lymphocytes". White blood cells are part of the immune system and help fight infections. In non-Hodgkin's lymphoma, lymphocytes grow abnormally and build up in the lymphatic system and around the body.

What was the purpose of this study?

In this study, the researchers wanted to learn more about 4 different combinations of drugs for non-Hodgkin's lymphoma. This was done to help researchers learn which combinations of drugs are the safest or most effective so they can be used in larger clinical studies.

The main questions the researchers wanted to answer in this study were:

- What signs and symptoms did the participants have?
- What medical problems did participants have during the study?

The answers to these questions are important to know before other studies can be done to find out if certain treatments help improve the health of people with non-Hodgkin's lymphoma.

What treatments did the participants get?

In this study, the participants were assigned to 1 of 4 treatment groups:

- **Group 1** got AZD9150 and acalabrutinib
- **Group 2** got AZD6738 and acalabrutinib
- **Group 3** got Hu5F9-G4, rituximab, and acalabrutinib
- **Group 4** got AZD5153 and acalabrutinib

This was an "open-label" study. This means the participants, researchers, study doctors, and other study staff knew what each participant was getting.

The chart below shows the treatment plan for the participants:

	Group 1	Group 2	Group 3	Group 4
	17 Participants	2 Participants	7 Participants	4 Participants
	• **AZD9150** through a needle into a vein	• **AZD6738** as a tablet by mouth	• **Hu5F9-G4** through a needle into a vein • **Rituximab** through a needle into a vein	• **AZD5153** as a tablet by mouth
	• **AZD9150** was given on days 1, 3, and 5, then once every week	• **AZD6738** was taken twice a day	• **Hu5F9-G4** was given once every week • **Rituximab** was given once every week for the first month, then every 4 weeks	• **AZD5153** was taken once a day
	• Took acalabrutinib as a capsule by mouth			
	• Took acalabrutinib twice a day			
	• Participants stayed in the study until their cancer got worse, or they decided to leave the study			

What happened during this study?

The study started in June 2018 and ended in March 2021.

Based on some of the medical problems the participants were having, and because some of the drugs were not effective in treating the participants' cancer, the researchers decided to end the study early.

Before the participants got study treatment, they visited their study site once. This part of the study lasted for up to 1 month. At this visit, the study doctors made sure the participants could join the study. They also:

- did physical exams and asked about the participants' medications and any medical problems they were having
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an "ECG"
- took images of the participants' swollen lymph nodes using a CT scan
- took a "biopsy", which is a small sample of the participants' cancer

The study doctors also did these tests and measurements throughout the study.

While the participants got study treatment, they visited their study site several times. The number of visits was different for each treatment group. This part of the study lasted for up to 1 year.

After the participants got study treatment, they visited their study site 2 or more times. They visited the study site 1 month after they finished treatment, then every 3 months. At these visits, the study doctors checked the health of the participants.

What were the results of this study?

This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

The websites listed at the end of this summary may have more information about the study results.

What signs and symptoms did the participants have?

To answer this question, the study doctors did tests and measurements before and after the participants got their study treatment.

The doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also did ECGs to check the participants' heart health.

Overall, the researchers found that there were some small changes in the results of these tests and measurements. But, the researchers did not consider these changes to be meaningful.

The study doctors also kept track of the "adverse events" that the participants had.

An adverse event is any sign or symptom that participants have during a study. Doctors keep track of all the adverse events that happen in studies, even if they do not think the adverse events might be related to the study treatment.

An adverse event is considered "serious" when it is life-threatening, causes lasting problems, or the participant needs hospital care.

Adverse events may or may not be caused by the treatments in the study. A lot of research is needed to know whether a treatment causes an adverse event.

The adverse events the participants had during this study are not in this summary. Because there was a very small number of participants in each treatment group, leaving this information out helps protect their identities.

For **Group 1** and **Group 3**, this study was stopped because some of the drugs were not effective in treating the participants' cancer. Studies investigating these drugs were not continued after the study.

For **Group 2** and **Group 4**, this study was stopped early due to the number of adverse events the participants were having. Studies investigating these drugs were not continued after the study.

What medical problems happened during this study?

The medical problems that the participants had during this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities.

The medical problems participants have during clinical studies that the study doctors think might be related to the study treatments are called "adverse reactions". An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study may or may not be caused by the study treatments. A lot of research is needed to know whether a treatment causes an adverse reaction.

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of 4 combination treatments in adults with non-Hodgkin's lymphoma.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies for any of these 4 combination treatments are not planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. If more information about the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03527147"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D9820C00001"** into the search box and click **"Find a Study"**.

Full Study Title: PRISM: A Platform Protocol for the Treatment of Relapsed/ Refractory Aggressive Non-Hodgkin's Lymphoma

Acerta Pharma BV Protocol Number: D9820C00001

National Clinical Trials Number: NCT03527147

Acerta Pharma BV sponsored this study and has its headquarters in Oss, The Netherlands.

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

Thank you

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

CISCRP

The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical studies, nor is it involved in conducting clinical studies.

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