

Clinical Trial Results



Research Sponsor: Eisai Ltd.

Drug Studied: Eribulin, also called E7389

Short Trial Title: A trial to learn if eribulin works and how safe it is for people with soft tissue sarcoma who have already tried chemotherapy

Thank you!

You took part in this clinical trial for the trial drug eribulin, also called E7389. You and all of the participants helped researchers learn more about eribulin to help people with a type of cancer known as soft tissue sarcoma. Soft tissue sarcomas form from the soft tissues of the body, such as fat and muscle.

Eisai, a Japanese pharmaceutical company and the sponsor of this trial, thanks you for your help. Eisai is committed to improving health through continuing research in areas of unmet need and sharing with you the results of the trial you participated in. Eisai prepared this summary with a medical and regulatory writing organization called Synchrogenix.

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

What has happened since the trial started?

The trial started in November 2011.

The sponsor of the trial reviewed the data collected up to November 2014 and created a report of the results. This is a summary of that report.

The trial included 52 participants from 13 sites in Japan. One of these participants did not receive treatment with the trial drug.

Why was the research needed?

Researchers were looking for a different way to treat people who have soft tissue sarcoma that is in an advanced stage or has spread to other parts of the body. The standard treatments for this type of cancer are surgery and other treatments that help shrink tumors. But these treatments may not help all people with later stages of the disease.

The researchers in this trial wanted to find out if eribulin works in a small number of people with different kinds of soft tissue sarcoma who had already tried chemotherapy. They also wanted to find out if people had any medical problems during the trial.

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

- How many participants had cancer that did not get worse after 12 weeks of treatment?
- What adverse events did participants receiving eribulin have? An adverse event is a medical problem that may or may not be caused by the trial drug.

What kind of trial was this?

To answer these questions, researchers asked for the help of men and women like you. The people in the trial were 28 to 73 years old. 45.1% of the people were male, and 54.9% of the people were female.

All of the people in this trial had soft tissue sarcoma that:

- Was advanced or had spread to other parts of the body
- Could not be cured with surgery or radiation
- Had gotten worse and needed more treatment

The people in the trial had different types of soft tissue sarcoma:

- 16 people had “adipocytic sarcoma”, also known as “liposarcoma”. This is a type of soft tissue sarcoma that grows from fatty tissue.
- 19 people had “leiomyosarcoma”. This is a type of soft tissue sarcoma that grows from the smooth muscles that line the body’s organs.
- 16 people had certain other types of soft tissue sarcoma.

This trial was “open-label”. This means that the participants, the trial doctors and staff, and the sponsor knew which drugs the participants received.

You received eribulin through a needle into your vein, also called an IV. The figure below shows how treatment was given in your trial.



What happened during the trial?

Before the trial started, the doctors did a full check-up to make sure each participant could join the trial.

The doctors also:

- Asked what medications each participant was taking
- Took blood and urine samples
- Scanned each participant’s tumors to see how advanced their cancer was
- Checked each participant’s heart health

During the trial, the participants received eribulin on day 1 and day 8 of each treatment cycle. A treatment cycle was 21 days long.

Throughout the trial, the doctors:

- Continued to check the participants' health, asked what medications they were taking, and took blood and urine samples
- Asked the participants how they were feeling and if they had any adverse events
- Scanned the participants' tumors every 6 weeks to see if their cancer was improving or getting worse
- Checked each participant's heart health

Each participant could continue receiving the trial drug until:

- Their cancer got worse
- They had an intolerable adverse event
- They decided to leave the trial

Their cancer was considered worse if their existing tumors got bigger or new tumors grew.

After their last dose, all participants:

- Had a trial visit 1 month later
- Had their tumors scanned every 6 weeks until their cancer got worse
- Were checked on by the doctors every 12 weeks

The figure below shows how the trial was done.

How did this trial work?

During the trial

All participants could continue receiving the trial drug until:

- Their cancer got worse
- They had an intolerable adverse event
- They decided to leave the trial

All participants received treatment on days 1 and 8 in 21-day cycles.

After the last dose

All participants:

- Had a trial visit 1 month later
- Had tumors scanned every 6 weeks until their cancer got worse
- Were checked on by doctors every 12 weeks

What were the results of the trial?

This is a summary of the main results of this trial up to November 2014. The results each person had might be different and are not in this summary. But the results each person had are part of the summary of results. A full list of the questions researchers wanted to answer can be found on the website listed at the end of this summary. If a full report of the trial results is available, it can also be found on this website.

Researchers look at the results of many trials to decide which treatment options may work best and are well tolerated. Other trials may provide new information or different results. Always talk to a doctor before making any treatment decisions.

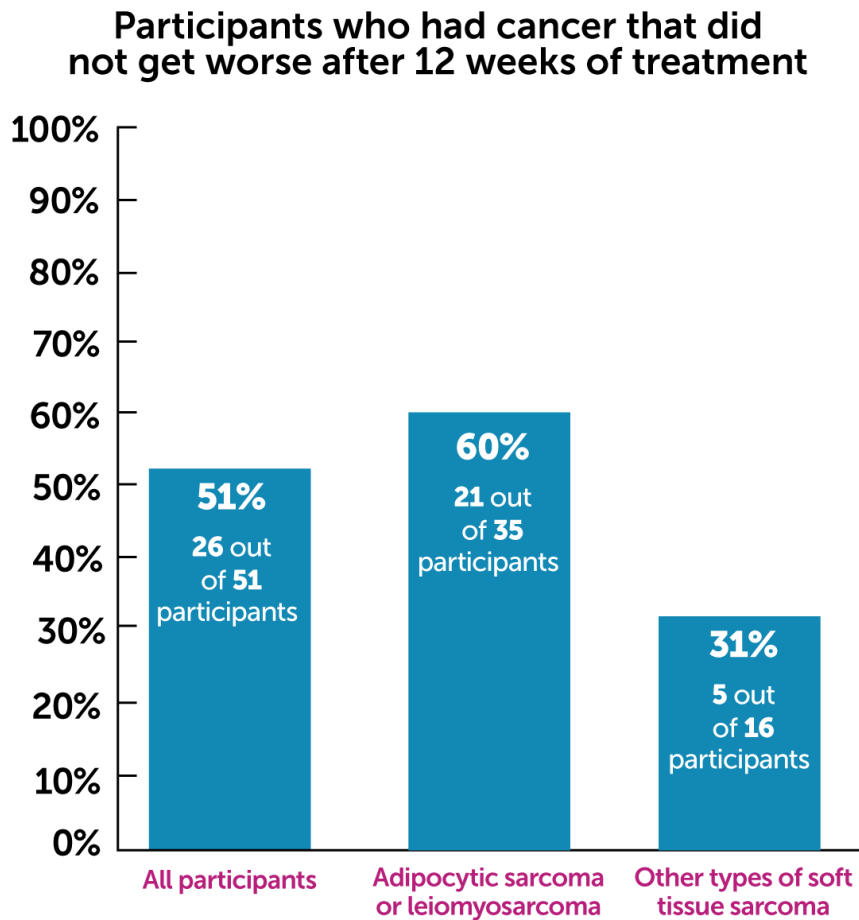
How many participants had cancer that did not get worse after 12 weeks of treatment?

Overall, 26 out of 51 participants (51.0%) had cancer that did not get worse after 12 weeks of treatment.

Of the 35 participants who had adipocytic sarcoma or leiomyosarcoma, 21 participants (60.0%) had cancer that did not get worse after 12 weeks of treatment.

Of the 16 participants who had other types of soft tissue sarcoma, 5 participants (31.3%) had cancer that did not get worse after 12 weeks of treatment.

The chart below shows how many participants had cancer that did not get worse after 12 weeks of treatment.



What medical problems did participants have?

Medical problems that happen in clinical trials are called “adverse events”. An adverse event is called “serious” when it is life-threatening, causes lasting problems, or the participant needs to be admitted to a hospital.

This section is a summary of the adverse events that happened during this trial. These medical problems may or may not be caused by the trial drug. The website listed at the end of this summary may have more information about the medical problems that happened in this trial. A lot of research is needed to know whether a drug causes a medical problem.

How many participants had adverse events?

In this trial, all 51 participants (100.0%) had adverse events.

The table below shows how many participants had adverse events in this trial.

Adverse Events in This Trial

	Out of 51 participants who received eribulin
How many participants had adverse events?	100.0% (51)
How many participants had serious adverse events?	29.4% (15)
How many participants stopped receiving the trial drug because of adverse events?	7.8% (4)

What were the most common serious adverse events?

In this trial, 15 out of 51 participants (29.4%) had serious adverse events.

The table below shows the serious adverse events that happened in 3% or more of participants. There were other serious adverse events, but these happened in fewer participants.

Most Common Serious Adverse Events in This Trial

	Out of 51 participants who received eribulin
Cancer pain	5.9% (3)
Intestinal blockage	3.9% (2)

In this trial, 1 out of 51 participants (2.0%) died due to a serious adverse event. This participant died from heart failure.

What were the most common adverse events?

In this trial, all 51 participants (100.0%) had adverse events.

The most common adverse events were low numbers of different types of white blood cells.

The table below shows the adverse events that happened in 30% or more of participants. There were other adverse events, but these happened in fewer participants.

Most Common Adverse Events in This Trial

	Out of 51 participants who received eribulin
Low numbers of white blood cells	100.0% (51)
Low numbers of white blood cells that help protect against infection	98.0% (50)
Low numbers of a type of white blood cell called lymphocytes	78.4% (40)
Low numbers of red blood cells	47.1% (24)
Cancer pain	45.1% (23)
Fever	41.2% (21)
Nausea	41.2% (21)
General discomfort	39.2% (20)
Constipation	31.4% (16)
Weakness, numbness, and pain in the hands and feet	31.4% (16)

How many participants had adverse reactions?

Adverse reactions are medical problems that the trial doctors thought were caused by the trial drug. An adverse reaction is called “serious” when it is life-threatening, causes lasting problems, or the participant needs to be admitted to a hospital. This section is a summary of the adverse reactions that happened during this trial.

In this trial, all 51 participants (100.0%) had adverse reactions. The table below shows how many participants had adverse reactions.

Adverse Reactions in This Trial

	Out of 51 participants who received eribulin
How many participants had adverse reactions?	100.0% (51)
How many participants had serious adverse reactions?	9.8% (5)
How many participants stopped receiving the trial drug because of adverse reactions?	3.9% (2)

What were the most common serious adverse reactions?

In this trial, 5 out of 51 participants (9.8%) had a serious adverse reaction. The table below shows all the serious adverse reactions that happened in this trial. None of the participants died due to a serious adverse reaction.

All Serious Adverse Reactions in This Trial

	Out of 51 participants who received eribulin
Bleeding in the liver	2.0% (1)
Bleeding in the tumor	2.0% (1)
Blood clot in the lungs	2.0% (1)
Fever with low numbers of white blood cells that help protect against infection	2.0% (1)
Fluid build-up around the lungs due to an infection	2.0% (1)
Infection by a bacteria in the <i>Streptococcus</i> family	2.0% (1)

What were the most common adverse reactions?

In this trial, all 51 participants (100.0%) had adverse reactions. The most common adverse reactions were low numbers of different types of white blood cells.

The table below shows the adverse reactions that happened in 30% or more of participants. There were other adverse reactions, but these happened in fewer participants.

Most Common Adverse Reactions in This Trial

	Out of 51 participants who received eribulin
Low numbers of white blood cells	100.0% (51)
Low numbers of white blood cells that help protect against infection	98.0% (50)
Low numbers of a type of white blood cell called lymphocytes	78.4% (40)
Low numbers of red blood cells	47.1% (24)
Fever	41.2% (21)
General discomfort	39.2% (20)
Nausea	37.3% (19)

How has this trial helped patients and researchers?

In this trial, researchers learned more about how eribulin may have helped people with certain types of soft tissue sarcoma.

Researchers look at the results of many trials to decide which treatment options may work best and are well tolerated. This summary shows only the main results from this one trial. Other trials may provide new information or different results.

Further clinical trials with eribulin are planned.

Where can I learn more about the trial?

You can find more information about this trial on the website listed below. If a full report of the trial results is available, it can also be found here:

- <http://www.clinicaltrials.gov> - Once you are on the website, type **NCT01458249** into the search box and click “**Search**”.

Full trial title: An Open-label, Multi-center, Phase 2 Study to Evaluate the Efficacy and Safety of Eribulin in Previously Treated Subjects with Advanced or Metastatic Soft Tissue Sarcoma

Protocol number: E7389-J081-217

Eisai, the sponsor of this trial, has headquarters in Tokyo, Japan, and regional headquarters in Woodcliff Lake, New Jersey, USA and Hatfield, Hertfordshire, UK. The phone number for general information is 44-845-676-1400.

Thank you

Eisai would like to thank you for your time and interest in participating in this clinical trial. Your participation has provided a valuable contribution to research and improvement in health care.



Eisai Co., Ltd. is a global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as “giving first thought to patients and their families and to increasing the benefits health care provides,” which we call our human health care (hhc) philosophy. With over 10,000 employees working across our global network of R&D facilities, manufacturing sites, and marketing subsidiaries, we strive to realize our hhc philosophy by delivering innovative products in multiple therapeutic areas with high unmet medical needs, including Oncology and Neurology. For more information, please visit

<http://www.eisai.com>.

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Synchrogenix Headquarters 2 Righter Parkway, Suite 205 Wilmington, DE 19803
<http://www.synchrogenix.com> • 1-302-892-4800