

The safety and effects of TTI-621 in combination with doxorubicin in people living with leiomyosarcoma

The full title of this abstract is: Safety and clinical activity of TTI-621 in combination with doxorubicin in patients with unresectable or metastatic high-grade leiomyosarcoma: Results from the low-dose expansion cohort.

VIEW ABSTRACT

Please note this summary only contains information from the scientific abstract:

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Study number: NCT04996004

Study start date: June 2021 Estimated Study end date: February 2024

Date of summary: June 2023

For more information on this study, go to: <https://www.clinicaltrials.gov/ct2/show/NCT04996004>

KEY TAKEAWAY

What are the key takeaways from this study?

- In this ongoing study, people received TTI-621 in combination with doxorubicin then TTI-621 alone as a treatment for leiomyosarcoma.
 - TTI-621 and doxorubicin are medications that are being researched to treat people living with leiomyosarcoma.
- The most severe side effects were thought to be caused by doxorubicin or the combination of doxorubicin with TTI-621, and fewer side effects were thought to be caused by TTI-621 alone.
 - A side effect is something expected or unexpected that you feel was caused by a medicine or treatment you take.
- Initial results show that after treatment with TTI-621 and doxorubicin, half of the people's tumors did not grow, and a quarter of the people's tumors shrank.

PHONETICS

Find out how to say medical terms used in this summary

Doxorubicin
<DOK-soh-ROO-bih-sin>

Macrophage
<MA-kroh-fayj>

Intravenous
<IN-truh-VEE-nus>

Metastatic
<meh-tuh-STA-tik>

Leiomyosarcoma
<LY-oh-MY-oh-sar-KOH-muh>

Unresectable
<UN-ree-SEK-tuh-bul>

GLOSSARY

CD47: a protein found on many cells but occurs at much higher levels on cancer cells. CD47 stops macrophages from removing cancer cells.

DNA: DNA contains genetic information that controls activity inside a cell.

Enzyme: a protein that speeds up chemical reactions in cells.

Leiomyosarcoma: a rare type of cancer that grows in smooth muscles.

Macrophage: a type of white blood cell that can surround and kill foreign substances (such as microorganisms) and remove dead cells and cancer cells.

Metastatic leiomyosarcoma: the tumor has spread to other parts of the body.

Smooth muscle: a type of muscle found in many parts of the body such as the digestive system, urinary system, uterus, and blood vessels.

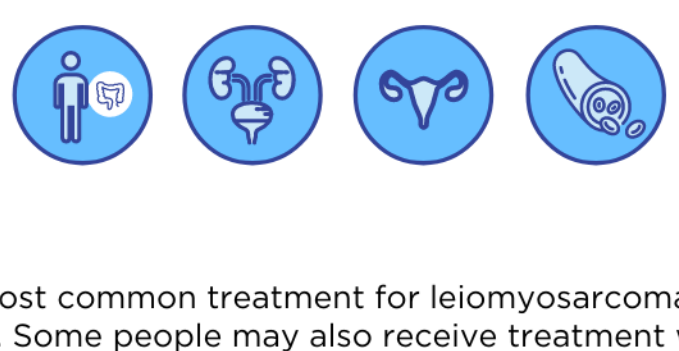
Tumor: an abnormal mass of tissue that may be cancer or may not be cancer.

Unresectable leiomyosarcoma: the tumor cannot be removed by surgery for many reasons, such as the size of the tumor, the stage of the cancer, and the location of the tumor.

INTRODUCTION

What is leiomyosarcoma?

- Leiomyosarcoma is a rare type of cancer that grows in smooth muscles

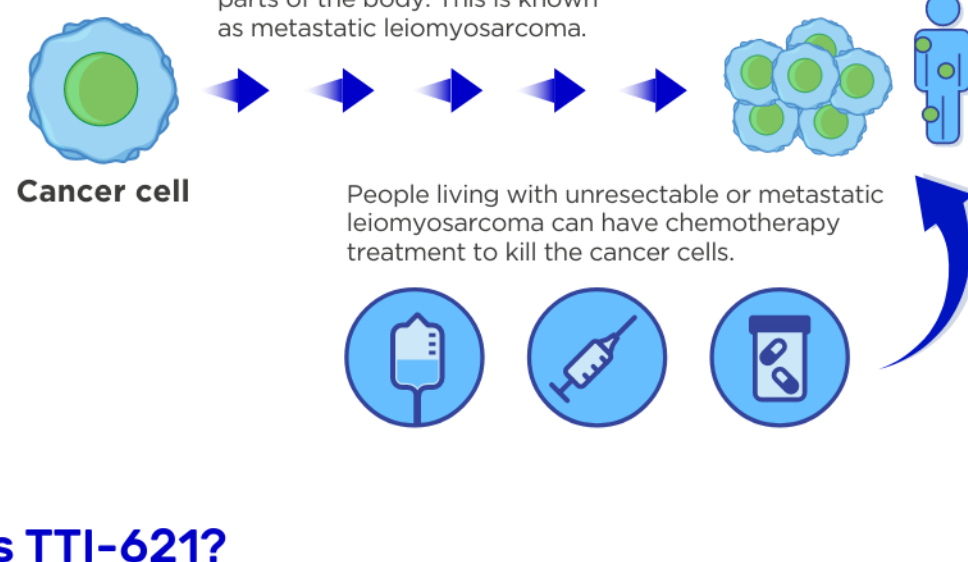


Smooth muscles are found in many parts of the body such as the digestive system, urinary system, uterus, and blood vessels.

Leiomyosarcoma is usually first found in the abdomen, pelvis, or uterus.

- The most common treatment for leiomyosarcoma is surgery that removes the tumor. Some people may also receive treatment with radiation before or after surgery, depending on where their tumor is located.
 - Treatment that uses radiation can destroy cancer cells by damaging their DNA.

- In some people, the tumor cannot be removed by surgery for many reasons, such as the size of the tumor, the stage of the cancer, and the location of the tumor. This is known as unresectable leiomyosarcoma.



The tumor may spread to other parts of the body. This is known as metastatic leiomyosarcoma.

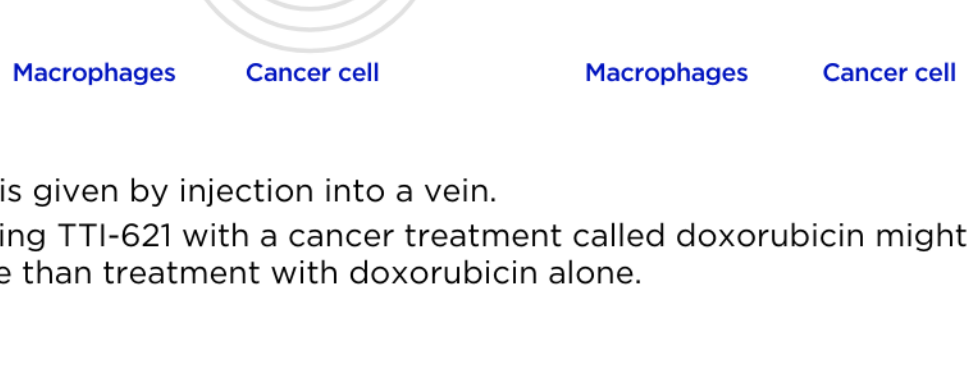
People living with unresectable leiomyosarcoma can have chemotherapy treatment to kill the cancer cells.

What is TTI-621?

- Researchers are looking at a medication called TTI-621 as a treatment for people living with leiomyosarcoma.
- TTI-621 may help people whose cancer did not respond well to previous treatment, such as people living with leiomyosarcoma in the advanced stage.
 - Advanced stage means that the cancer has spread from where it first started to nearby tissue, lymph nodes, or distant parts of the body.
 - TTI-621 is not approved to treat people living with advanced leiomyosarcoma. This is why it is being researched.

High CD47 on surface of cancer cell stopping removal by macrophages

TTI-621 stops CD47 activity on surface of cancer cell allowing removal by macrophages

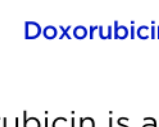


- TTI-621 is given by injection into a vein.
- Combining TTI-621 with a cancer treatment called doxorubicin might be more effective than treatment with doxorubicin alone.

What is doxorubicin?



Doxorubicin damages DNA in cells and may kill cancer cells. It also blocks a certain enzyme needed by cells to help them divide and repair DNA.



Doxorubicin is given by injection into a vein.

Doxorubicin is used alone or with other medications to treat many types of cancer.

- Doxorubicin is a standard treatment for people living with advanced leiomyosarcoma.

What does this summary describe?

- In an ongoing study, researchers are looking at how safe and effective TTI-621 combined with doxorubicin is in people living with advanced leiomyosarcoma.
 - These study participants received TTI-621 combined with doxorubicin for some time, and then they received TTI-621 without doxorubicin.
 - “How effective” in this context means how well a medicine works within a clinical trial.
- The side effects that people had when receiving TTI-621 combined with doxorubicin, as well as the side effects people had when receiving TTI-621 alone.
 - A side effect is something (expected or unexpected) that might have been caused by a medicine or treatment you take.
- How well people's cancer responded to treatment.
 - This means that the researchers checked to see if the cancers disappeared, shrank, stopped growing, or still grew while receiving the treatment.

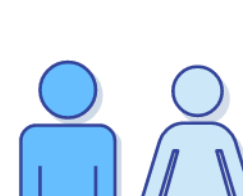
Researchers wanted to find out...

- How safe it was for people receiving TTI-621 combined with doxorubicin.
- If people's cancer disappeared, shrank, or stopped growing with treatment.



STUDY DETAILS

Who took part in this study?



23 people aged over 18 years living with advanced leiomyosarcoma took part and received:



First TTI-621 + Doxorubicin

39% of people had received prior treatment for advanced leiomyosarcoma

Then only TTI-621

- By the data cutoff date of October 3, 2022, researchers had data to check all 23 people for the safety of the treatment and 20 people for the effects of the treatment.

RESULTS

What were the results of this study?

Side effects

- The treating doctors thought that some of the side effects were caused by one or both medicines.

They thought:

9% of people had severe side effects that were caused by TTI-621 only

30% of people had severe side effects that were caused by TTI-621 and doxorubicin together

74% of people had severe side effects that were caused by doxorubicin only

of these 30% of people:

13% A lower than normal number of neutrophils in the blood (a type of white blood cell that helps fight infection)

9% Low levels of white blood cells in the blood (white blood cells help fight infection)

9% Low levels of platelets in the blood (a component of blood that helps to form clots)

3

2

2

of these 74% of people:

35% A lower than normal number of neutrophils in the blood (a type of white blood cell that helps fight infection)

30% Low levels of white blood cells in the blood (white blood cells help fight infection)

26% Low levels of neutrophils (a type of white blood cell that help to fight infections)

8

7

6

Each person could have more than 1 side effect

Effectiveness

- Some people responded to treatment with TTI-621 combined with doxorubicin:

0% had tumors that disappeared (called a complete response)

25% of people who had tumors that shrank (called partial response)

55% of people who had tumors that did not grow (called stable disease)

This summary reports the results of a single study. The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence, not on the results of a single study.

CONCLUSIONS

What were the main conclusions of this study?

- In this ongoing study, researchers found that:
 - Side effects of TTI-621 combined with doxorubicin could be dealt with without difficulty in people living with leiomyosarcoma.
 - Some people living with advanced leiomyosarcoma responded to treatment with TTI-621 combined with doxorubicin.

MORE INFORMATION

Who sponsored this study?

This study was sponsored by Pfizer Inc.

Pfizer Inc.
235 42nd St.
New York, NY 10017
Phone (United States): +1 212-733-2323

Pfizer would like to thank everyone who took part in this study.

Where can I find more information?

More information can be found in the scientific abstract of this study, which you can access here:

[View ASCO Scientific Abstract >](#)

<https://www.clinicaltrials.gov/ct2/show/NCT04996004>

For more information on clinical trials in general, please visit:

<https://www.clinicaltrials.gov/ct2/about-studies/learn>

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are>

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