Axi-STS Trial

A clinicopathological phase II study of axitinib in patients with advanced angiosarcoma and other soft tissue sarcomas

Lay Summary of Clinical Trial Results

Introduction

Researchers look at the results of many trials to understand which drugs work and how they work. It takes a lot of participants in many trials from all around the world to advance medical science. This summary only shows the main results from the Axi-STS trial, other trials might find different results or provide new information.

The trial was sponsored by Sheffield Teaching Hospitals NHS Foundation Trust and coordinated by the Cancer Research UK Clinical Trials Unit at the University of Birmingham. The research was approved and funded by Cancer Research UK and Pfizer Ltd.

We want to thank all the participants of this trial and their caregivers who helped the researchers learn more about using a drug called axitinib in patients with advanced angiosarcoma and other soft tissue sarcomas. We hope this summary will help them understand and feel proud of their important role in medical research.

This summary is for information purposes only. If you need medical advice, please contact your doctor. If you participated in this trial and have questions about the results, please speak with a doctor or other staff member at the trial site.

Why was this research needed?

Before a treatment is available to all patients, researchers run clinical trials to get information about how well the treatment works and about how safe it is.

The researchers in this trial wanted to learn how well a drug called axitinib worked for people with advanced angiosarcoma and soft tissue sarcoma. Localised sarcomas can be cured by surgery with or without additional radiotherapy. However, advanced sarcomas have a poor outcome despite treatment with chemotherapy, so better treatments are needed.

Axitinib works by interfering with the formation of new blood vessels, which is critical for the growth of the tumour. Recent studies have shown that this type of drug could help with tumour shrinkage and improve survival.

What were the main questions studied?

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

- If axitinib could improve the length of time that a patient lives with the disease without it getting worse
- If axitinib could make the tumour shrink
- If axitinib could improve how long people live

Who participated in the trial?

Patients diagnosed with soft tissue sarcoma that was incurable by surgery or radiotherapy, that may not have responded to standard chemotherapy or may not be suitable for chemotherapy treatment.

What treatments did the participants take?

All patients had axitinib 5mg tablet by mouth twice daily for two years unless the disease got worse or the patient developed unmanageable side effects.

If the patients had very bad side effects, their doctor could choose to reduce the number of tablets they took or stop the treatment completely after discussing with them.

What happened during the trial?

Before deciding to take part in the trial, all the patients were provided with detailed information about it. They could also discuss it with their families and clinical team before agreeing to take part. This is called “informed consent.” Then the doctors and nurses asked the patients about their medical history and checked their health to make sure they could join the trial.

Patients had some tests done before taking part in the trial, these tests included:

- Assessment of the cancer
- Physical examination
- Computerised Tomography (CT) or Magnetic Resonance Imaging (MRI) scan
- Chest x-ray
- Electrocardiogram
- Blood tests
- Urine tests

Patients attended a clinic once a week for the first four weeks of treatment, then every four weeks until the end of treatment. At each clinic visit, they were asked about any symptoms and side effects, had a physical examination and a routine blood test. A chest x-ray was done at the start of the trial, at weeks four, eight and twelve and then every twelve weeks. CT and/or MRI scans were done to measure their tumours before trial entry, then every twelve weeks.

What were the results of the trial?

This is a summary of the main results from this trial. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

A total of 145 patients were recruited between 31st August 2010 and 29th January 2016 from 13 UK hospitals in to four different groups:

- 38 angiosarcoma patients
- 37 leiomyosarcoma patients
- 36 synovial sarcoma patients
- 34 other sarcoma subtypes patients

The results showed that:

- In 54 (45%) out of the 121 patients that could be evaluated, their disease did not get worse within the first 12 weeks of treatment. This suggests that axitinib was having some anti-tumour effect. This was seen in the angiosarcoma, leiomyosarcoma and synovial sarcoma groups.
- In six patients (5%) out of the 121 patients that could be evaluated, their tumour had shrunk within 12 weeks.
- In 16 patients (12%) out of 136 patients that started trial treatment, the disease did not get worse within 12 months.
- Fifty-four patients (40%) were still alive at 12 months.

The research team also looked at the side effects on each group. Side effects are unwanted medical events that happen during the trial and are reported because the trial doctor believes the side effects were related to the treatment in the trial.

The most common problems reported by patients taking axitinib were tiredness, raised blood pressure, mouth or gut (bowel) becomes sore and inflamed, feeling sick, shortness of breath and loss of appetite. These side effects were comparable to those experienced by patients on other studies with axitinib. All 136 patients experienced at least one side effect over the course of the trial.

A medical problem reported during a clinical trial that puts the participant's life at risk, requires hospitalisation, causes disability, causes a baby being born with medical problems, or may have turned into one of these problems if not treated, is called a serious adverse event. These may be related to the patient's disease, trial treatment or other causes.

In total 74 serious adverse events were reported across 56 patients (41.2%), of the 74 adverse events, two (3%) were categorised as fatal/life threatening. As shown by these numbers some participants had more than one serious adverse event. However, only 34 (46%) of these 74 adverse events were considered to be likely related to the trial treatment.

Overall, the results showed that axitinib has activity in some patients with advanced angiosarcoma, leiomyosarcoma, synovial sarcoma and other sarcoma types and is well tolerated.

How has this trial helped patients and researchers?

The results of the Axi-STS trial are an important step towards identifying new active drugs in the treatment of soft tissue sarcoma. The results of the trial would support further research into the use of this drug in a wider group of patients.

Where can I learn more about the trial?

You can find more information about this trial at the website listed below:

- https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-axitinib-advanced-soft-tissue-sarcoma-Axi-STS
- https://www.isrctn.com/ISRCTN60791336

If you have questions about this trial, you can also contact the trial team by e-mail at: axi-sts@trials.bham.ac.uk

Trial information

Short trial title:	Axi-STS
Full trial title:	A clinicopathological phase II study of axitinib in patients with advanced angiosarcoma and other soft tissue sarcomas
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Name of Research Ethics Committee:	NRES Committee West Midlands-Edgbaston
Research Ethics Committee reference number:	09/H1208/42
IRAS ID:	13431
EudraCT number:	2008-006007-23
ISRCTN:	60791336
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