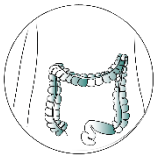
A pancreatic cancer clinical trial



Investigating the use of study drug – a somatostatin analog versus placebo before surgery to prevent pancreatic fistula, a surgical complication

PAC.5 | NCT06807437

What is the purpose of this study?

The purpose of this study is to find out if adding a study drug prior to surgery could prevent a pancreatic fistula after surgery in patients with pancreatic cancer or a pancreatic lesion that could become cancerous.

The study drug is a somatostatin analog, a synthetic version of a hormone made by the body—It is believed to help stop the body from making extra hormones and keep certain types of tumour cells from growing.

Why is this study important?

The usual surgical care is a distal pancreatectomy is surgery to remove parts of the pancreas to treat pancreatic cancer or a pancreatic lesion that could become cancerous. A pancreatic fistula can occur when a small leak from the pancreas causes fluid to collect. This can sometimes lead to infection or other problems. This study will test to see if this injectable drug when given prior to surgery can prevent pancreatic fistula but it is not clear if it can offer better results than surgery alone.

Who can participate in this study?

This trial is for people:

- 18 years old and above.
- with confirmed diagnosis of pancreatic cancer or a pancreatic lesion with malignant potential.
- who have planned to have an elective distal pancreatectomy occur within 60 days after registration to the trial.

This trial is not for people:

- with a prior diagnosis of malabsorption syndrome.
- who have been treated with radiation therapy for their pancreas malignancy at any time prior to enrolment in the trial.
- pregnant or nursing (nursing includes breast milk fed to an infant by any means, including from the breast, milk expressed by hand, or pumped).

SHARE THIS SUMMARY WITH YOUR HEALTH CARE TEAM
TO SEE IF THIS TRIAL IS A GOOD OPTION FOR YOU.

What are the risks?

If you choose to take part in this study, there is a risk that the new drug may not be as good as the standard surgery alone. There is also a risk that you could have side effects from the new drug. Some of the most common side effects that the study doctors know about are diarrhea, pain and tenderness in the belly from the gallbladder (gallstones or sludge), nausea, pain, swelling and redness at the injection site, pain in muscles, vomiting, headache, low blood pressure.

You will find details of all side effects in the consent document.

What can I expect?

If you choose to take part in this study, you will be randomly placed in one of two groups. In Group 1 you will receive the new drug before surgery. In Group 2, you will receive a placebo before surgery.

In this study, you will also be asked to complete a few questionnaires at different times, to follow your health and understand your Quality of Life.

How can I find out more or join the study?

Talk to your cancer doctor if you are considering joining this study. You can share summaries like this with them and ask if they think joining the trial may be a good option for you.

Before you join this study, you will be asked to review an *Informed Consent* document which will tell you more about why the research is being done and your role as a participant. You will have an opportunity to discuss anything that is not clear and ask any questions you have.

Joining this study is entirely up to you and you can decide to leave at any time without giving a reason. Your decision to join or leave the trial will not affect your standard medical care.

The **PAC.5 study** is currently enrolling patients at cancer centres in Canada. For a full list of participating cancer centres please visit www.clinicaltrials.gov and search using NCT06807437.

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