A gynecological cancer clinical trial

Treatment of early stage vulvar cancer based on tumour features

VU.2 | NCT06358469

What is the purpose of this study?

The purpose of this study is to evaluate if specific testing of vulva cancer tissue that is removed by surgery provides useful information to help decide if additional surgery is required or not.

Why is this study important?

The usual approach to treating early-stage vulvar cancer consists of a single surgery to remove the cancer.

Treating early-stage vulvar cancer based on specific testing of the tissue that has been removed may identify people who require additional surgery to prevent the cancer from returning. This testing may also identify people who do not need a second surgery which can have negative health and sexual effects.

Who can participate in this study?

This trial is for people 18 years of age or older who have early-stage vulvar cancer and have had surgery to remove the cancer.

What are the risks?

If you choose to take part in this study, you could receive either more surgery or no additional surgery. If you undergo a second surgery, there is a risk you would have more side effects. If you do not undergo a second surgery, there is a risk that the tumour may have a greater chance of returning. You will find details of all side effects in the consent document and by speaking with your doctor.

What can I expect?

If you decide to take part in this study, the laboratory testing results of the vulvar tissue that was removed will be reviewed to verify if you are able eligible for the trial. If you are enrolled, additional surgery or no further surgery will be recommended. You will be followed on the trial for a minimum of 36 months after enrollment and as long as the study remains open.

In this study, you will also be asked to complete a few questionnaires at different times, for the researchers to 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 VU.2 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 NCT06391242.