

PHASE II STUDY OF ORGAN PRESERVATION IN EARLY RECTAL CANCER PATIENTS

A SUMMARY FOR PATIENTS

What is the Phase II Study of Organ Preservation in Early Rectal Cancer Patients?

It is a clinical trial to test if chemotherapy followed by local surgery and then chemotherapy and radiation therapy given at the same time (CRT), is effective to treat patients who have early stage, low risk rectal cancer. This would be instead of a major surgery that would lead to a colostomy. A colostomy is an opening into the colon from the outside of the body that provides a new path for waste to leave the body.

What is a clinical trial?

A clinical trial is a type of research study done by doctors to test new treatments, or new ways to give those treatments.

Why is this study being done?

We are doing this study because researchers believe it is possible to treat patients without major surgery.

Here is what we already know:

- For patients with rectal cancer the standard treatment is major surgery followed by chemotherapy and radiation therapy given at the same time (CRT). Or CRT may be given before surgery in certain cases.
- Major surgery can lead to many side effects that affect quality of life. These include trouble urinating, sexual dysfunction, and a colostomy.

Now we want to answer questions like:

- Can we treat low risk patients with chemotherapy followed by local surgery and then CRT in order to preserve their rectal function?

What treatments are being used in this trial?

In this study you will get chemotherapy followed by surgery, followed by CRT. The treatments being used are:

• **FOLFOX**

This is the chemotherapy given before surgery. FOLFOX is 3 drugs given one after the other.

They are:

- o 5-fluorouracil (5-FU) -once every 14 days (2 weeks) for 12 weeks

- o Oxaliplatin—once every 14 days (2 weeks) for 12 weeks
- o Leucovorin –once every 14 days (2 weeks) for 12 weeks

After each treatment, you will also go on an infusion pump of 5-FU for 46 hours.

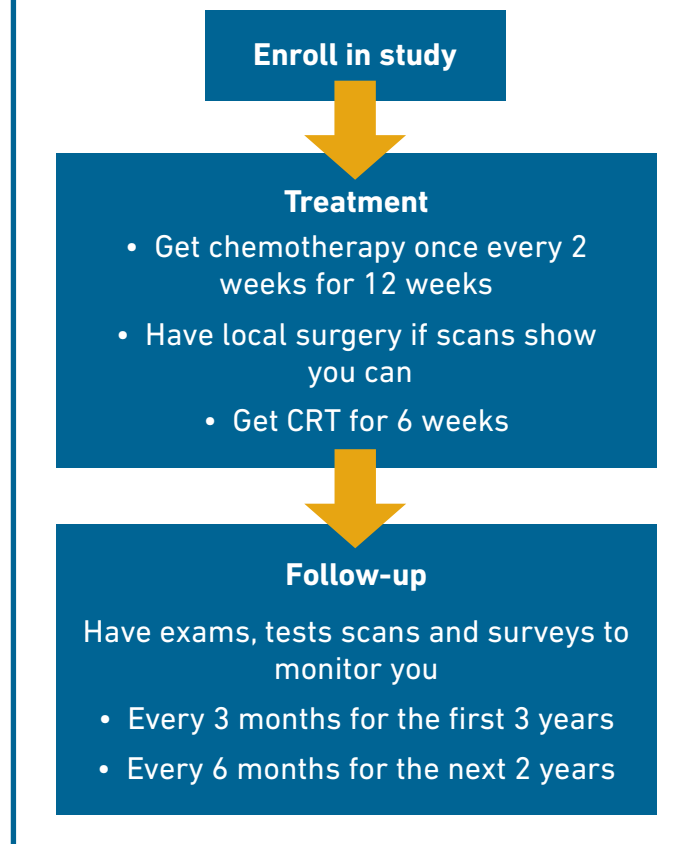
• **Local Surgery**

Once the chemotherapy is done, you will have:

- o Scans to see if you can have local surgery
- o Have surgery 6-12 weeks after the chemotherapy is finished

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What will treatment in this study look like?



(Continued from front)

- **CRT**

- o 4-12 weeks after local surgery
- o Radiation- five days a week for 6 weeks
- o Chemotherapy- 5-FU through an infusion pump starting the first day of every week. It is removed at the end of each week of radiation. Your doctor may switch from 5-FU to Capecitabine, which you take by mouth.

What are some of the side effects caused by this treatment?

You may have side effects while on this study. The doctor running the study will tell you about all of the possible side effects before you decide to take part. All patients taking part in this study will be watched closely and treated for any side effects.

What will I have to do on the clinical trial?

Before you decide to take part in the trial you will:

- Meet with a doctor and study coordinator before your treatment to talk about your medical history, medicines you are taking, and about your ability to do your daily activities
- Have an exam, blood and other tests, to find out if you can be in the study

During the study you will:

- Get FOLFOX chemotherapy for 12 weeks
- Have local surgery
- Get CRT for 6 weeks
- Have exams, blood tests and scans to monitor you
- Be asked to give samples of your blood for research
- Complete 3 surveys to rate your bowel function, your sexual function, and quality of life

After the treatment is done you will:

- Be followed every 3 months for the first 3 years after treatment, and then once every 6 months for the next 2 years.
- Have an exam, blood tests, and scans to monitor you. You will also have a sigmoidoscopy every 6 months during the first 3 years

- Complete 3 surveys to rate your bowel function, your sexual function, and quality of life
- Have a colonoscopy at 1 and 3 years after local surgery

Will insurance cover the cost of this trial?

Some health plans will not pay the costs for people taking part in studies. You should check to find out what they will pay for. Taking part in this study may or may not cost more than the cost of getting routine cancer treatment.

Is this trial right for me?

If you would like to learn more about taking part in this trial, let your doctor know. You can talk about whether this trial is right for you. Before you decide to join the study, your doctor will help you learn all the facts through a process called informed consent.

What if I change my mind after starting the trial?

You can leave the study at any time. Tell the study doctor if you are thinking about stopping or decide to stop treatment. They will tell you how to stop safely. Leaving this trial will not affect your present or future care at Fox Chase Cancer Center.

Is there any reason why my doctor would stop me from taking part?

Yes, the doctor may decide to take you off the study if:

- They feel it is best for your health
- The research study is stopped

Who is running the trial?

Doctors and researchers at Fox Chase Cancer Center are running this study.

Where can I learn more?

If you have any questions about this study please talk to your doctor or call the:

Office of Clinical Research/215-214-1515

For questions about your rights while taking part in a study, you may call the:

Institutional Review Board / 215-214-3754

Fox Chase Cancer Center/215-214-3754



Fox Chase Cancer Center is an NCI-Designated Comprehensive Cancer Center



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