

You're Invited to Take Part in an Important Research Study

A Phase 3, Multicenter, Open-Label Study to Test the Diagnostic Performance of Copper Cu 64 PSMA I&T PET/CT in Staging of Men With Newly Diagnosed Unfavorable Intermediate-Risk, High-Risk, or Very-High-Risk Prostate Cancer Electing to Undergo Radical Prostatectomy With Pelvic Lymph Node Dissection



What is this study for?

You have been invited to be in a research study. Before you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve. Please read this leaflet carefully.

- We are testing an investigational diagnostic product called copper Cu 64 PSMA I&T Injection for positron emission tomography (PET)/computed tomography (CT) scans
- We are measuring how safe and effective this product is for taking pictures of prostate cancer tumors in the body
- We must test this product to find out whether the pictures can be used to correctly stage your prostate cancer
- The US Food and Drug Administration (FDA) requires this testing because copper Cu 64 PSMA I&T Injection is investigational in the United States. This means that it has not been approved by the FDA and may be used only as part of this clinical trial
- If you choose to participate, you will be compensated for your time and the expenses you incur as part of the research study
- You do not have to participate in this study, and you can choose to stop participating at any time

What to expect

1 Screening Visit

Screening should take about 1 hour and may be conducted on Imaging Day.

- You'll be asked to sign an informed consent form—this is to make sure that you understand and agree to the terms of the study
- The doctor will review your medical and medication history
- Your blood pressure, pulse, and breathing rate will be measured

2 Study Visit 1 (Imaging Day)

This visit may take up to 5 hours and will include

- Measurements of your blood pressure, pulse, and breathing rate before and after you receive copper Cu 64 PSMA I&T Injection
- Measurement of your weight
- A conversation with the doctor about your medications

The Imaging Scan:

- You will receive a dose of copper Cu 64 PSMA I&T Injection
- One to 4 hours after the injection, you will have pictures called PET/CT scans taken of your body. During the scans you will need to lie still for no more than 45 minutes on a flat bed that slides into the scanner

3 Follow-up Phone Call (1-2 days after Imaging Day)

This phone call may take up to 30 minutes.

- The doctor will ask if you have had any side effects since you received copper Cu 64 PSMA I&T Injection

4 Surgery Follow-up (up to 90 days after Imaging Day)

- If you elect to have surgery as part of your medical care for prostate cancer, the surgery will be scheduled within 60 days of Imaging Day. Information from the surgery will be used for the research study

What are the risks?

Your participation in this study may involve the following risks:

- The imaging scans using copper Cu 64 PSMA I&T Injection involve exposure to radiation. Any radiation exposure carries a risk of cancer developing, which may happen many years after exposure. Your study doctor will discuss this radiation exposure with you and help ensure you are not exposed to an unsafe amount of radiation



What your participation means

This study is being performed for research purposes only to assess the safety and effectiveness of copper Cu 64 PSMA I&T Injection. It cannot be promised that you will receive any medical benefits from participating in this study.

However, your participation in the trial is very important. Your help could lead to the approval of a new diagnostic agent to be used in staging prostate cancer.

THANK YOU!

We're very grateful for your time.



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