

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

Status: Recruiting

Eligibility Criteria

Sex: Male

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- newly diagnosed with prostate adenocarcinoma with intermediate / high risk features - planned prostatectomy with pelvic lymph node dissection - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- received any therapy for prostate cancer before surgery - not able to have a PET scan - had a prostate-specific membrane antigen (PSMA) PET scan in the past 90 days

Conditions & Interventions

Conditions:

Cancer

Keywords:

Clinics and Surgery Center (CSC), Prostate Cancer

More Information

Description: The purpose of this study is to test the safety and effectiveness of Copper Cu 64 PSMA I&T in detecting lesions during a PET scan. This study is open to men with newly diagnosed prostate cancer who plan to have a prostatectomy and lymph node removal. Copper Cu 64 PSMA I&T is an investigational PET imaging agent, given to you via IV injection, similar to the way other imaging agents are used in many other types of scans. Cu 64 specifically targets the prostate specific membrane antigen (PSMA) that is found on the surface of metastatic prostate cancer cells. Increased image contrast may make it easier for the doctor to see smaller lesions compared to other imaging agents.

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Phase: PHASE3

IRB

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