

RESEARCH STUDY



Disease

Prostate Cancer that no longer responds to standard therapies

Protocol Title

An Open-Label, Phase II Efficacy Trial of the Implantation of Mouse Renal Adenocarcinoma Cell-Containing Agarose-Agarose Macrobeads in the Treatment of Patients with Castration-Resistant Prostate Cancer Resistant to Docetaxel

Principal Investigator & Contact Information

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Study Status

Recruiting (*pending IRB approval*)

Brief Summary of Protocol

This phase II study is evaluating the safety (health risks and side effects) and efficacy of The Rogosin Institute's investigational (not approved by the Food and Drug Administration) macrobeads. The macrobeads are small sugar-coated beads containing cancer cells from a mouse kidney cancer cell line and are surgically placed in the abdomen of patients with prostate cancer who did not respond to standard therapies.

Potential candidates for this study are males 18 years of older, with a minimum life expectancy of 16 months, with prostate cancer. As indicated above, eligible candidates must have failed standard hormonal therapy and chemotherapy, and have no alternative treatment. Medical conditions indicating that the surgical implantation of the beads would involve an unacceptably high risk for the individual would not be eligible to participate.

The study is divided into a maximum of 4 implantations of beads, each separated by 4 months, with regular follow-up visits between implantations and after the fourth implantation. The study involves a screening phase, the surgical implantation(s) of the macrobeads, repeat blood and urine work, follow-up clinical visits and regular imaging studies. Regardless of the number of implantations, subjects will be followed-up by the study team throughout their lifetime.

Treatment Overview (Potential Benefits)

There is no guarantee that participants will receive direct benefit from this study. Participation in this study may add knowledge about the macrobeads that may one day help others with cancer.

Study Sponsor

The Rogosin Institute
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IRB Information

Weill Cornell Medical College IRB
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