

RESEARCH STUDY

WCMC
IRB APPROVED
Approved:
3.25.10
Expires:
11.22.10

Disease

Pancreatic cancer or colorectal cancer that no longer responds to standard therapies

Protocol Title

An Open-Label, Phase 2 Efficacy Trial of the Implantation of Mouse Renal Adenocarcinoma Cell-Containing Agarose-Agarose Macrobeads in the Treatment of Patients with Treatment-Resistant, Metastatic Pancreatic Adenocarcinoma or Colorectal Cancer

Principal Investigator & Contact Information

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Study Status

Recruiting

Brief Summary of Protocol

This phase 2 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 implanted in the abdominal cavity of patients with pancreatic or treatment resistant colorectal cancers.

Potential candidates for this study are males or females, 18 years of older, with a minimum life-expectancy of 16 months. 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

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IRB Information

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