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TITLE: Position Emitter I124 Iododeoxyuridine as a Tracer to Follow DNA Metabolism on Scans and in Tumor Samples in Advanced Breast Cancer: Comparison of 18F 2-Fluor-2-Deoxy-(D)-Glucose, as a Tracer for Glycolysis

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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14. ABSTRACT This protocol has been approved by our IRB and Radioactive Drug Research Committee. Accrual began in 2005 following approval from the sponsor. Several patients have been enrolled on this study. The tumor uptake on the IUDR PET scans was not as prominent as anticipated, in comparison with the FDG PET scan. We plan to treat an additional 4 patients. If there is no evidence of significant uptake in known tumor sites then we will consider replacing IUDR with another agent such as FLT.					
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Introduction: The objectives of this study are: 1) to determine whether the biologic activity of advanced breast cancer as measured by retention of ^{124}I IUDR on PET scans pre and post systemic therapy is different between patients whose tumor shrinks in comparison to those whose tumor is stable or grows, 2) to compare pre and post-treatment results of FDG-PET scanning and IUDR-PET scanning in the same breast cancer lesions as a basis for assessment of the metabolic change during systemic therapy, 3) to further assess the biologic activity of metastatic tumor sites and their change in size following systemic therapy by PET scans in comparison with other standard parameters such as CT and bone scans.

Body: A total of 4 patients were enrolled on the trial. However, three patients elected to withdraw consent for different reasons. All of the patients who initially agreed to participate, had expressed an understanding of the research procedures when they consented. One patient withdrew prior to the first PET scan due to social issues with a family member. The second patient withdrew after the first PET scan, also due to social reasons. The third patient changed her mind and withdrew prior to the first PET scan due to declining health and family issues.

One patient completed the study. The tumor uptake on the IUDR PET scans was not as prominent as anticipated, in comparison with the FDG PET scan. This may be due to rapid breakdown of the IUDR. Therefore, we plan to enroll 4 more patients on this trial. If there is no evidence of significant uptake in known tumor sites with the IUDR PET scan, then we can be fairly certain that this will not be a useful agent. At that point we would consider replacing IUDR with another agent such as FLT.

One patient was hospitalized with complaints of abdominal pain within a few days prior to the second series of PET scans. The pain was considered to be due to tumor and unrelated to the material utilized on this study. This was reported to the IRB.

Key Research Accomplishments: Please see the Body.

Reportable Outcomes: None.

Conclusion: As noted above we plan to enroll 4 additional patients and then determine whether another agent should replace the ^{124}I IUDR.

References: None.

Appendices: None.

Supporting Data: Attached is the IRB approval from 1/06 regarding continuation of this study.



Institutional Review Board/Privacy Board

TO: Theresa A Gilewski, MD
Department of Medicine/Breast Service

FROM: Roger S Wilson, MD
Chairman, Institutional Review Board/Privacy Board

A handwritten signature in black ink, reading "Roger S. Wilson".

DATE: 01/11/2006

RE: Continuing Review Report for Protocol # 97-046

Your request for continuation of Protocol # 97-046 entitled "Positron Emitter II24 Iododeoxyuridine to follow DNA Metabolism on Scans and in Tumor Samples in Advanced Breast Cancer: Comparison to 18f 2-Fluoro-2-Deoxy-(D)-Glucose, as a Tracer for Glycolysis", was reviewed at the 01/10/2006 Institutional Review Board/Privacy Board Meeting and was approved for 12 months.

Please submit an amendment to update the informed consent into the new required Q/A template.