



Non-Technical Abstract

Radioiodine therapy of thyroid cancer allows effective treatment for patients who harbor metastatic deposits of that tumor and contributes to the good prognosis that most patients with that form of cancer enjoy. However, it is only effective for thyroid cancer, because only thyroid cells have the ability to concentrate iodine from the blood stream. This ability is due to the presence of a iodide transporter (called the sodium-iodide symporter or NIS) in thyroid cells that is not expressed in other cell types. The study we plan to perform is designed to insert this transporter into prostate cancer cells so that they too may be treated with radioiodine.

The study includes men with prostate cancer that has recurred locally in the pelvis after external beam radiation therapy. The men who consent will have a virus that will cause expression of the NIS gene injected directly into the prostate during a procedure under general anesthesia. 3 days after the injection, they will be given a small, tracer dose of radioactive iodine in order to measure how much uptake of radioiodine has been induced within the prostate. If the amount of uptake is seen to be sufficiently high, they will, on day 4, be given a therapeutic dose of radioiodine that will have the potential to kill the cancer cells. They will be carefully observed in the Clinical Research Unit for toxic effects of the virus and the radioiodine as well as for tumor responses to the therapy.

Because the thyroid may also be affected by the radioiodine therapy, we will give the patients a tablet of thyroid hormone (Cytomel[®]) to take prior to the therapy in order to block uptake of radioiodine by the thyroid. We will also monitor the thyroid function carefully and should a decline occur, it can be fully and easily corrected through administration of thyroxine replacement therapy, as is done routinely for millions of patients with hypothyroidism worldwide.

This study is the first of its kind and has the potential for opening a new avenue of therapy for cancers of many types, including prostate, that is currently available only for thyroid cancer. The current proposal is the first step in this direction and will answer the first important questions about the safety and potential efficacy of the process for non-thyroid malignancies.