**INTRODUCTION**

Radium-224 loaded seeds [stainless steel] are inserted into solid tumors and release by recoil short-lived alpha-emitting atoms (Rn-220, Po-216, Pb-212, Bi-212, Po-212, Tl-208). These atoms disperse in the tumor and spray it with highly destructive alpha radiation. The decay products diffuse in the tumor mass to a distance of at least 5 mm. **AIMS**

A. Examine the ability of alpha radiation emitting seeds to destroy malignant tumors in mice.

B. Examine the induction of anti-tumor immunity following ablation of the tumor by alpha radiation emitting wires.

C. Initiate a clinical trial to test the effect of Alpha DaRT seeds in SCC cancer patients.

**MATERIALS AND METHODS**

Radium-224 loaded seeds [stainless steel] are inserted into solid tumors and release by recoil short-lived alpha-emitting atoms (Rn-220, Po-216, Pb-212, Bi-212, Po-212, Tl-208). These atoms disperse in the tumor and spray it with highly destructive alpha radiation. The decay products diffuse in the tumor mass to a distance of at least 5 mm.

**CLINICAL TRIAL**

A) Feasibility and safety clinical study started for 35 patients with skin or head and neck squamous cell carcinoma. Tumor size ≤ 5 centimeters in the longest diameter. Ra-224 loaded Alpha DaRT Seeds, each carrying a low dose of 2 µCi, will be placed to achieve 39Ra activity of about 5 µCi per gram of tumor. CT will be used to check the position of the radioactive seeds. Four weeks after treatment the seeds will be removed.

B) Three patients ages 78-94 were treated by DaRT seeds. Seeds were implanted under local anesthesia.

- A patient with skin SCC was implanted with 37 seeds for 4 weeks. Tumor shrinkage was evident with no side effects.
- A patient with SCC in the ear received 5 seeds for 21 days. Considerable tumor shrinkage was evident with no adverse effects.
- A patient with SCC of the tongue, 2 cm longest diameter, was treated with 8 seeds for 5 days. No adverse effects were observed.

C) CT scan (axial cut) of DaRT seeds implanted in a patient with skin SCC on the face (A) on day of treatment (B) and after 5 days (C).

**SUMMARY**

- DaRT seeds were able to destroy mouse and human Tumors of different histological origin.
- DaRT relies on alpha particles and thus, may be effective against hypoxic tumors.
- DaRT seeds can be produced with various intensities, sizes and shapes and enable custom designed seeds for individual patients to deliver a more effective and conformal treatment to non-resectable tumors and metastatic lesions.
- DaRT is characterized by negligible gamma radiation and is thus safer for physicians during intervention and to patient post treatment.
- DaRT can be combined with other treatment modalities such as external beam radiation, surgery, chemotherapy and immunotherapy.