A New Alpha Particle Treatment for Recurrent or Aggressive Head and Neck Squamous Cell Carcinoma

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INTRODUCTION

The first clinical trial in humans with skin and head and neck squamous cell carcinoma (SCC) was performed in order to evaluate the effect of a unique intratumoral alpha radiation-based tumor ablation treatment termed Diffusing Alpha-emitters Radiation Therapy (DaRT).

AIM

The feasibility and safety clinical study is ongoing and currently 27 cases were treated at the Rabin Medical Center (Israel) and IRST (Italy). Patients with histopathologically confirmed skin or head and neck SCC, and tumor size ≤ 5 centimeters in the longest diameter, were included. Treatment was delivered based on a CT-simulation pre-treatment plan. The seeds (1 cm long and 0.7 mm in diameter) each carrying a dose of 2 µC were placed up to 5 millimeters from each other. CT was used to check the position of the radioactive seeds. Two to four weeks after implantation, the seeds were removed and six weeks after treatment, CT was performed to assess the effect of treatment. Study results are available for 18 cases who were treated per protocol and reached the 30-day visit. The age of the patients ranged between 60 to 102 (median 80). Nine patients had head and neck SCC and eighteen subjects were diagnosed with aggressive skin SCC. Thirteen subtypes were treated within radiation failure trials (Radiation therapy vs. Q). All tumors responded to the treatment. Thirteen tumors had a complete response and five tumors showed a partial response. No major toxicity was noted.

METHOD

Radon-224 loaded sources (DaRT seeds) were inserted into solid tumors and released by recoil short-lived alpha-emitting atoms (Rn-220, Po-216, Pb-212, Bi-212, Po-212, Ti-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 approximately 5 mm around the seed.

RESULTS

DataRT seed releases alpha-emitting atoms. The recoiling atoms disperse in the tumor, forming a cluster of alpha emissions covering several millimeters. The alpha radiation cause double-strand breaks in DNA, dissolves the tumor and remains encapsulated within its alpha-emitter.

KEY ELIGIBILITY CRITERIA

Inclusion Criteria
- Histopathological confirmation of SCC
- Lesions ≤ 5 cm in the longest diameter (without nodal spread)
- Age ≥ 18
- WOCBP will have evidence of negative pregnancy test
- Life expectancy ≥ 6 months
- ECOG ≥ 2

Exclusion Criteria
- Unичecked lesion
- Tumor of Keratoacanthoma histology
- Patients with morbid diseases, autoimmune diseases or of obesity.
- Patients under immunosuppressive and/or corticosteroid treatment.
- Participation in other studies in the past 30 days

EFFICACY

A feasibility and safety clinical study is ongoing and currently 27 cases were treated at the Rabin Medical Center (Israel) and IRST (Italy). Patients with histopathologically confirmed skin or head and neck SCC, and tumor size ≤ 5 centimeters in the longest diameter, were included. Treatment was delivered based on a CT-simulation pre-treatment plan. The seeds (1 cm long and 0.7 mm in diameter) each carrying a dose of 2 µC were placed up to 5 millimeters from each other. CT was used to check the position of the radioactive seeds. Two to four weeks after implantation, the seeds were removed and six weeks after treatment, CT was performed to assess the effect of treatment. Study results are available for 18 cases who were treated per protocol and reached the 30-day visit. The age of the patients ranged between 60 to 102 (median 80). Nine patients had head and neck SCC and eighteen subjects were diagnosed with aggressive skin SCC. Thirteen subtypes were treated within radiation failure trials (Radiation therapy vs. Q). All tumors responded to the treatment. Thirteen tumors had a complete response and five tumors showed a partial response. No major toxicity was noted.

SAFETY

Initial tumor volume (cm³) 2.82
Alpha DaRT seeds inserted 24
Total activity kBq 2,100
Response 100%

CONCLUSIONS

- DaRT exhibit enhanced radiobiological potential.
- DaRT treatment was effective against radio-resistant SCC tumors without major toxicity.
- DaRT is characterized by negligible gamma radiation and is thus safer for physicians during intervention and to patient post treatment.

CONTACT INFORMATION
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PATIENT EXAMPLE

AT 22 – Procedure Date: August 30st, 2018

Screening 27/08/2018
DaRT insertion 30/08/2018
Day 30 30/09/2018