



ReSTART Clinical Study

FOR THE TREATMENT OF RECURRENT SCC OF THE SKIN

A New Clinical Trial

AlphaTAU

YOUR PATIENT HAS BEEN DIAGNOSED WITH RECURRENT CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC)

You can now offer the Alpha DaRT® treatment, a new minimally invasive modality

AlphaDaRT®

A NOVEL INTRALESIONAL
RADIUM-224 THERAPY FOR
SKIN CANCER PATIENTS



For more information, please email us at info@alphatau.com



WHAT IS ALPHA DART®

Alpha DaRT utilizes alpha particles that are released directly into the lesion by the decay chain of radium-224.

Alpha particles, due to their large mass and high linear energy transfer, are extremely destructive to cancerous cells by a mechanism that directly leads to clustered, double-strand DNA breaks, independent of oxygen presence.

The treatment involves the minimally-invasive insertion of sources coated with radium-224 which are designed to release radiotherapeutic alpha-emitters directly into the lesion. The radium-224 sources are delivered into the lesion, and are then removed approximately two weeks later.

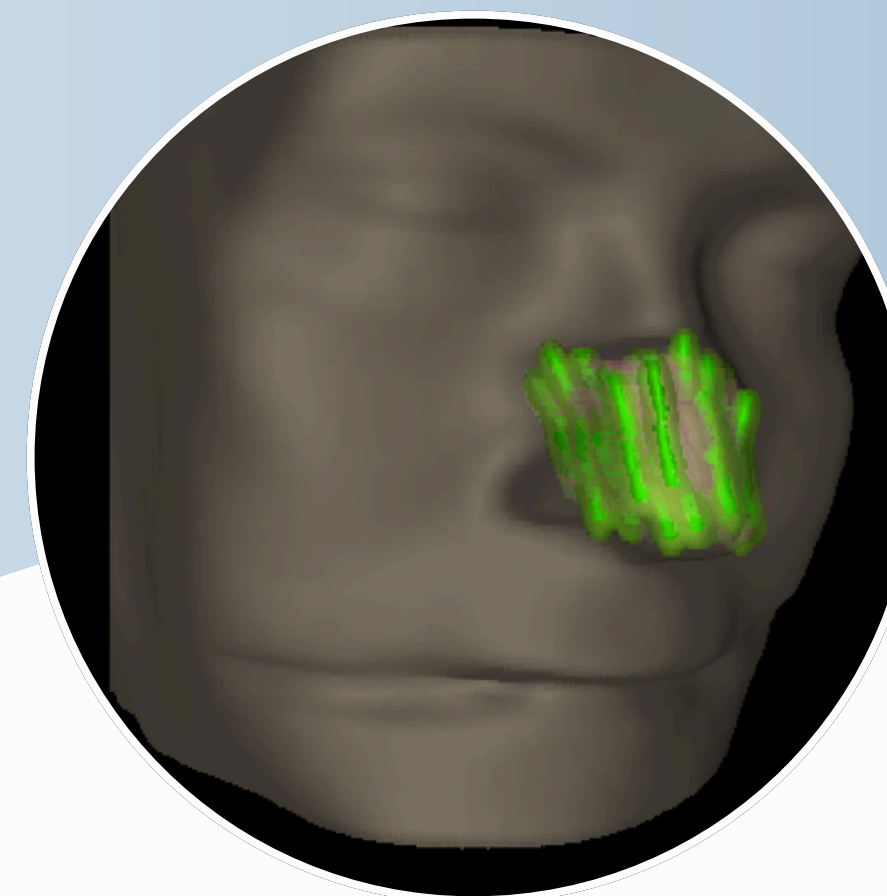
Both the insertion and removal procedures are performed on an outpatient basis usually under local anesthesia.



Before



Insertion



CT visualization



After (1 year)

PATIENT 68-YEAR-OLD MALE - SCC NOSE



**Patient
with cSCC**

Recurrent lesion

THE RESTART TRIAL

ELIGIBILITY CRITERIA



Inappropriate

For any standard of
care treatments or
due to surgery fatigue



Standard of care

Surgery / Radiation / Systemic
therapy

AlphaDeRT

Intralesional

Radium-224 Therapy

ReSTART is a prospective, multicenter clinical trial for the treatment of recurrent SCC of the skin. The primary objective is to determine the objective response rate and the duration of response at 6 months, and secondary objectives include assessing safety, overall survival, as well as other endpoints.

For a complete clinical trial information, please visit: <https://clinicaltrials.gov/study/NCT04377360>

CLINICAL PROGRESS

POTENTIAL ADVANTAGES



Precise Treatment

Direct intralesional placement



Well-Tolerated Toxicity Profile

Grade 2 or below; no chronic toxicity



Individualized Treatment

Personalized treatment planning to ensure optimal treatment effect

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FDA Breakthrough Device Designations

- SCC of the skin or oral cavity without curative standard of care
- Recurrent GBM

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Published Clinical Articles

- JAMA Open Network ¹
- Red Journal ²
- Journal of Contemporary Brachytherapy ³
- Cancers ⁴

> 30

Publications

Clinical / Pre clinical / Physics



Minimally-Invasive Procedure

Mostly performed under
local anesthesia



Reduced exposure risk for Patients & Caregivers

Due to Alpha particles
inherent physical properties



Limited side effects

Less chance of scarring or need
for reconstructive surgery

100%

Complete Response

US Multicenter Pilot Skin Cancer Trial Results, published in JAMA Network Open: 100% complete response (CR) in 10 patients at 12 weeks post-treatment; no device-related serious adverse events (SAE's) or systemic toxicity observed.

> 20

Open Clinical Trials

Across indications such as: Pancreas, Skin, Head & Neck, Lung, Breast, Prostate, Vulvar and Combination therapies (DaRT + immunotherapy)

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Countries

USA, Japan, Canada, France, UK, Italy and Israel



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The treatment includes a device for investigational purposes only and is not approved for use outside of a clinical trial

TO REFER YOUR PATIENTS

References :

1. D'Andrea MA, VanderWalde NA, Ballo MT, et al. Feasibility and Safety of Diffusing Alpha-Emitter Radiation Therapy for Recurrent or Unresectable Skin Cancers. *JAMA Netw Open*. 2023;6(5):e2312824. Published 2023 May 1.
2. Popovtzer A, Rosenfeld E, Mizrahi A, et al. Initial Safety and Tumor Control Results From a "First-in-Human" Multicenter Prospective Trial Evaluating a Novel Alpha-Emitting Radionuclide for the Treatment of Locally Advanced Recurrent Squamous Cell Carcinomas of the Skin and Head and Neck. *Int J Radiat Oncol Biol Phys*. 2020;106(3):571-578.
3. Bellia SR, Feliciani G, Duca MD, et al. Clinical evidence of abscopal effect in cutaneous squamous cell carcinoma treated with diffusing alpha emitters radiation therapy: a case report. *J Contemp Brachytherapy*. 2019;11(5):449-457.
4. Popovtzer A, Mizrahi A, D'Andrea MA, et al. Extended Follow-Up Outcomes from Pooled Prospective Studies Evaluating Efficacy of Interstitial Alpha Radionuclide Treatment for Skin and Head and Neck Cancers. *Cancers (Basel)*. 2024;16(13):2312. Published 2024 Jun 24.