clinical studies

solid tumor

Longitudinal Assessment of Responses to Salvage or Palliative Radiation Therapy after Progression on Systemic Immunotherapy

Treating Patients with Metastatic Cancer

PRINCIPAL INVESTIGATOR

James Welsh, MD
Professor Radiation Oncology
MD Anderson Cancer Center

SITE ENROLLING

The study has 5 locations.
Houston, Texas, USA
Leading Center: **MD Anderson Cancer Center**

ClinicalTrials.gov ID:
NCT0271025

artidis

Timely Diagnosis | Optimized Therapy

Phase 2 | Type **Interventional** | Allocation: **N/A** | Interventional Model **Single Group Assignment** king
Masking **None (Open Label)** | Primary Purpose **Treatment**

Brief Summary

This phase II clinical trial evaluates the safety, optimal dosing, and therapeutic efficacy of radiation therapy in patients with metastatic or progressive cancer following treatment with immune checkpoint inhibitors. The study aims to determine whether radiation can effectively control disease progression in patients whose tumors have demonstrated resistance or relapse after immunotherapy. By assessing adverse events and tumor response, the trial explores the potential of radiation therapy as a salvage or adjunctive strategy to enhance disease control in the post-immunotherapy setting.

Clinical Relevance

While immunotherapy has significantly improved outcomes in advanced cancers, a substantial subset of patients experience disease progression and require effective salvage strategies. This trial harnesses the immunomodulatory effects of radiation therapy—particularly its capacity to induce systemic antitumor responses through the abscopal effect—to potentially re-sensitize resistant tumors and augment immunotherapeutic efficacy. In addition to assessing clinical outcomes such as survival and quality of life, the study incorporates ARTIDIS as a clinical endpoint. By stratifying patients based on their ARTIDIS Nanomechanical Signature, the trial aims to evaluate whether this biophysical profiling tool can optimize treatment selection and serve as a cost-effective, precision-guided method for enhancing patient outcomespatient outcomes.

Study Schema

Study Population

Patients with stage IV metastatic cancer exhibiting progressive disease despite ongoing treatment with standard-of-care immunotherapy agents.

No. of ptients
230

Age
≥18y

Study Duration & Read-Outs

Enrollment Start
2016

Expected duration
10 years

Clinical Follow Up
1 year

Artidis Related Endpoint Readout

6 months
after measurement

Primary Objective

1. To identify immunotherapy-based treatment regimens in which salvage radiation therapy achieves systemic disease control following initial progressive disease (PD).
2. To determine whether specific immunotherapy combinations are associated with a higher incidence of treatment-related toxicities when followed by salvage radiation therapy.

Secondary Objective

1. To assess the frequency and durability of systemic disease control following salvage radiation therapy in patients who have progressed on immunotherapy and to correlate these findings with clinical response patterns and survival outcomes, including progression-free survival (PFS) and overall survival (OS).
2. To evaluate whether the nanomechanical properties of metastatic tumors, as characterized by the ARTIDIS Nanomechanical Signature, can serve as a predictive biomarker for response to RadScopal™ salvage radiation therapy (both high- and low-dose regimens) in patients administered after progression on immunotherapy.
3. To investigate the biological impact of sequential radiation therapy on tumor tissue nanomechanics— specifically, changes in the ARTIDIS Nanomechanical Signature following progression on immunotherapy—and to evaluate their association with clinical outcomes and treatment response.

Key Exclusion

- Confirmed diagnosis of malignancy, established through histological or cytological evaluation.
- Evidence of disease progression, defined by immune-related response criteria (irRC), occurring either:
  - During a prior clinical trial,
  - As part of standar-of-care treatment involving an immune checkpoint inhibitor or, cell-base immunotherapy, or when a clinical indication for salvage radiation therapy (e.g., for palliation) exists, as determined by the treating physician or principal investigator.
- Confirmed diagnosis of malignacy, established through histological or cytological evaluation.
- Prior documented disease progression while receiving immunotherapy, including checkpoint inhibitors

Key Inclusion

- Presence of active autoimmune disease, including but not limited to scleroderma, systemic lupus erythematosus (SLE), or other clinically significant rheumatologic conditions, that, in the judgment of the treating radiation oncologist, would contraindicate safe administration of radiation therapy.
- History of radiation therapy within the preceding 3 months involving treatment fields that are expected to overlap with the planned high-dose region, based on the clinical assessment of the treating radiation oncologist.

SPONSOR & PARTNERS

Sponsor
MD Anderson Cancer Center

Collaborator
Artidis AG

PRINCIPAL INVESTIGATOR

James Welsh, MD
Professor Radiation Oncology
MD Anderson Cancer Center

Abbreviations: RT- radiation therapy, irRC-immune related response criteria, PD-progressive disease

For any questions about this study or to express your interes in participating, please reach out to our research team at:

communication@artidis.com
www.artidis.com
Basel · Houston · Barcelona

 ISSUE DATE: 2025-11 VC-CP-006-v002