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

MD Anderson Cancer Center
Houston, Texas, USA

ClinicalTrials.gov ID:
NCT02710253

artidis
Timely Diagnosis | Optimized Therapy

Phase 2 | Type: **Interventional** | Allocation: **N/A** | Interventional Model: **Single Group Assignment**
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. Building on prior evidence that tumor nanomechanical properties correlate with response to radiation–immunotherapy combinations (Puebla-Osorio et al. 2024, Front. Oncol.), this study incorporates Artidis nanomechanical assessment as an exploratory endpoint to investigate correlations with salvage radiation therapy 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 patients
230

Age
≥18y

Study duration & readouts

Enrollment start
2016

Expected duration
10 years

Clinical follow up
1 year

Artidis related endpoint readout at

6 months
after measurement

Primary objectives

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 objectives

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 explore, as a hypothesis-generating secondary endpoint, whether tumor nanomechanical properties measured by the Artidis platform correlate with clinical outcomes following salvage radiation therapy, building on prior preclinical evidence (Puebla-Osorio et al. 2024).
3. To assess changes in tumor tissue characteristics over time and evaluate their association with clinical outcomes following salvage radiation therapy.

Key exclusion criteria

- 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 standard-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 criteria

- 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.

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Collaborator
Artidis AG

PRINCIPAL INVESTIGATOR

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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 interest in participating, please reach out to our research team at:

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