

# Trial Of Stereotactic Body Radiation Therapy (SBRT) for Oligoprogression on Immune Checkpoint Inhibitors (ICI) in Metastatic Renal Cell Carcinoma

NCT04974671

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	Yale University
<b>Enrollment</b>	30 participants

## Plain Language Summary

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This study is testing whether targeted radiation (Stereotactic Body Radiation Therapy, or SBRT) delivered to a small number of growing tumour spots can help people with metastatic kidney cancer stay on their current immunotherapy treatment for longer.

**\*\*You may be eligible if...\*\***

- You are 18 years or older with confirmed metastatic renal cell carcinoma (kidney cancer that has spread)
- Your most recent treatment is an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab), which you have been receiving for at least 3 months
- You have developed "oligoprogression" — meaning only a small number of tumour spots (up to 5) have grown while the rest are stable or responding
- Your general health is adequate (ECOG 0–2) and life expectancy is over 6 months

**\*\*You may NOT be eligible if...\*\***

- More than 5 tumour sites are progressing at the same time
- You are not currently on immunotherapy or it has been more than 3 months since your last dose
- You have been on your current immunotherapy for less than 3 months
- Your performance status or life expectancy is too low

Talk to your doctor to see if this trial is right for you.

## Key Eligibility Criteria

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### Inclusion (25)

- In order to be eligible for participation in this trial, the subject must:
- Be willing and able to provide written informed consent/assent for the trial
- Be e 18 years of age on day of signing informed consent.
- Have histologically confirmed renal cell carcinoma with metastatic disease detected on imaging. Biopsy of metastasis is preferred but not required
- The subject has a performance status of 0, 1, or 2 on the ECOG Performance Scale

... and 20 more (see full listing online)

### Exclusion (14)

- The subject must be excluded from participating in the trial if the subject
- Has had radiation therapy within 2 weeks of the first protocol treatment.
- Has brain-only oligoprogression. subjects with brain and systemic oligoprogression can still be considered, however treatment of brain metastases will be per standard of care prior to receiving study SBRT.

<https://clinicaltrials.gov/study/NCT04974671>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

- Has a diagnosis of immunodeficiency or is receiving systemic steroid therapy or any other form of immunosuppressive therapy within 2 weeks of the first protocol treatment. The use of lowdose steroids for management of chronic conditions is allowed (up to 12mg prednisone orally per day or the equivalent).
  - Has had prior radiation therapy within 2 weeks of the first protocol treatment.
- ... and 9 more (see full listing online)

## Locations (1 total)

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Yale University, New Haven, Connecticut, United States