



Do you have kidney cancer (renal cell carcinoma) that has spread to 2–5 other locations in your body?

If so, you may be able to participate in this study of a potential new treatment.

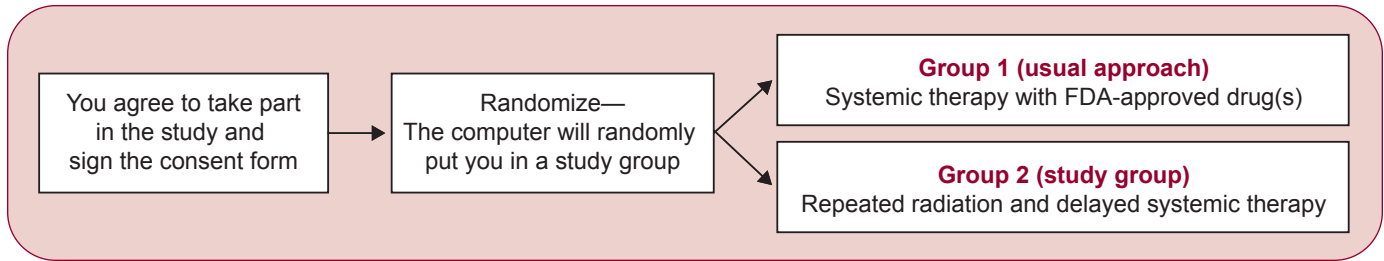
Focused Radiation versus Systemic Therapy for Kidney Cancer Patients with Limited Metastasis

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches for kidney cancer (i.e., renal cell carcinoma).
 - When kidney cancer has spread, it is referred to as metastatic kidney cancer.
- The usual treatment approach for metastatic kidney cancer is treatment with a Food and Drug Administration (FDA)-approved drug or drug combination. This approach is also often referred to as “systemic therapy” because it uses substances that travel through the bloodstream, reaching and affecting cells all over the body.
- The purpose of EA8211/SOAR is to compare:
 - The usual treatment of systemic therapy (i.e., therapy with drugs), to
 - A type of focused radiation therapy called stereotactic ablative radiation (SAbR) aimed directly at places in the body where there is cancer; SAbR will be given as long as it works to control the cancer and will be followed by systemic therapy (when SAbR alone is unable to shrink your cancer).
 - » SAbR delivers radiation to the metastasis with high precision in 1–5 treatments. Studies have shown that SAbR is effective for controlling kidney cancer. It also usually has fewer side effects and can be given in a shorter timeframe than systemic therapy.
- The researchers leading EA8211/SOAR believe that patients with 2–5 sites of metastatic kidney cancer, even if treated with radiation therapy, likely have additional invisible sites of metastasis (i.e., micro-metastasis) that are too small to detect. Researchers think it may be better to delay systemic therapy for these patients by using SAbR to treat the limited visible metastasis, as well as any new metastatic sites that reach a certain size that may develop.
 - Specifically, EA8211/SOAR aims to find out if radiation therapy is equal to or better than the usual treatment for patients with a limited number of metastatic sites. The study is also looking to see if SAbR has fewer side effects, with the potential to improve quality of life for patients.

WHAT does this study involve?

- If you decide to take part in this study, you will be assigned by chance (randomized) to one of two groups:
 - **Group 1:** You will get the usual FDA-approved drug(s) used to treat your cancer, either 1) as a pill you take by mouth, 2) through a vein in the arm, or 3) both, depending on which drug or drug combination you are receiving, as decided together by you and your oncologist.
 - **Group 2:** You will get SAbR (i.e., the focused radiation) to all visible/detectable metastatic sites that have reached a certain size. SAbR will be continued for any new metastatic sites (reaching a certain size) that may develop and that can be treated with SAbR. Eventually, if SAbR is not possible anymore (for example, because you have a metastasis in a location not treatable by radiation), you will receive the standard FDA-approved drug(s).



- After you finish your treatment, your doctor will continue to follow your condition for up to 10 years with a phone call every 3 months.

WHO will take part in this study?

- Approximately 500 people will participate in EA8211/SOAR (~250 people in each group).
- Participants must have renal cell carcinoma and 2-5 sites of metastatic kidney cancer that are treatable with SAbR.
- You can decide to stop taking part in the study at any time, even after you have enrolled.

WHAT are the costs of taking part in this study?

- Just as you would if you were getting the usual care for your cancer, you and/or your insurance plan will need to pay for the medical care you get as part of EA8211/SOAR. Check with your insurance company to find out what they will pay for.
 - You/your insurance plan will not have to pay for exams, tests, and procedures done for research purposes only, or that are covered by the study. Check with your doctor to find out what these might be.
- Taking part in this study may also mean that you need to visit the clinic or hospital more often than if you were getting the usual treatment for your cancer.
- You will not be paid for taking part in this study.

IF you would like to know more

- About the EA8211 study, talk with your doctor, or:
 - Visit www.ecog-acrin.org and search EA8211, then select the link to the EA8211 Home Page.
 - » If you are seeking information about the locations where the study is available, scroll down the page to Locations and Contacts and click the + sign.
 - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).
- About clinical trials:
 - General cancer information: visit the NCI website at www.cancer.gov
 - Insurance coverage: visit www.cancer.gov/clinicaltrials/learningabout/payingfor
- About ECOG-ACRIN:
 - Visit www.ecog-acrin.org
 - For a list of patient resources and links to patient advocacy groups, visit <https://ecog-acrin.org/patients/resources>

