



Do you have prostate cancer that has returned after prostatectomy?

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

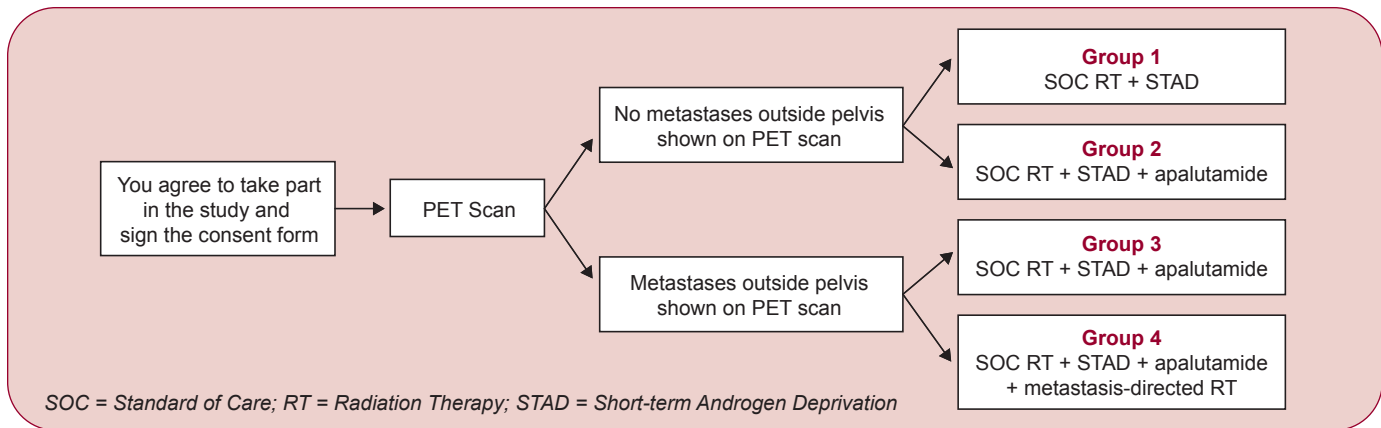
Treating Prostate Cancer That Has Come Back after Surgery with Apalutamide and Targeted Radiation Based on PET Imaging

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches for treating prostate cancer.
- In the EA8191/INDICATE study, all participants will receive the usual treatment for prostate cancer that recurs after surgery, which is radiation therapy (RT) to the prostate bed and pelvic lymph nodes, combined with short-term (6 months) androgen deprivation therapy (STAD), also sometimes referred to as hormone therapy. In addition:
 - Depending on the results of their initial PET scan, some patients will receive additional PET imaging, and/or metastasis-directed radiation therapy.
 - Some patients will also receive a type of hormone therapy called apalutamide, which is approved by the Food and Drug Administration (FDA) for treatment of prostate cancer.
- To decide which of these approaches is better, the study team will be looking to see if your cancer responds, and if it returns again, how much time passes between your treatment and when it returns.

WHAT does this study involve?

- **If your PET scan does not show evidence that your cancer has spread outside of the pelvis, you will be assigned by chance (randomized) to Group 1 or Group 2:**
 - Group 1: You will get the usual treatment for prostate cancer that comes back after surgery (RT and STAD via injections or oral pills) for 6 months. The injections will be either monthly, every 3 months, or just once during the 6-month period; the oral pills will be taken daily.
 - Group 2: You will get the usual RT and STAD treatment, plus apalutamide (240 mg pill taken by mouth, daily) for 6 months.
 - There will be about 210 people in Group 1 and 210 people in Group 2.
- **If your PET shows evidence that your cancer has spread outside of the pelvis, you will be assigned by chance (randomized) to Group 3 or Group 4 (Note: Some patients will undergo a second PET scan up to 12 months after treatment is completed, depending on the type of tracer used during the first PET):**
 - Group 3: You will get the usual RT and STAD treatment, plus apalutamide (240 mg pill taken by mouth, daily) for 6 months.
 - Group 4: You will get the usual RT and STAD treatment, plus apalutamide (240 mg pill taken by mouth, daily) and metastasis-directed RT (to the areas seen on your PET scan) for 6 months.
 - There will be about 120 people in Group 3 and 120 people in Group 4.



- After you finish your study treatment, your doctor will continue to follow your condition.
 - You will be seen approximately once every 3 months for the first 2 years, then once every 6 months during the following 3 years. For the remaining years of follow-up, you will be seen annually.

WHO will take part in this study?

- Approximately 660 men will participate in EA8191/INDICATE.
- Participants must be at least 18 years old, with evidence of biochemical recurrence (a rise in the blood level of prostate-specific antigen [PSA]) after radical prostatectomy, and **no** evidence of metastases on conventional imaging.
- You can decide to stop taking part in EA8191/INDICATE at any time, even after you have enrolled.

WHAT are the costs of taking part in this study?

- Just as when you receive usual care for your cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you get as part of this study. Check with your insurance company to find out what they will pay for.
- You/your insurance provider will **NOT** have to pay for the apalutamide (if you are in Group 2, 3, or 4) or the second PET scan/tracer used for the PET scan (if you are in Group 3 or 4).
- Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer.
- You will not be paid for taking part in EA8191/INDICATE.

IF you would like to know more

- About the EA8191/INDICATE study, talk with your doctor, or:
 - Visit www.ecog-acrin.org and search EA8191, then select the link to the EA8191 Home Page.
 - » For 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/paying for cancer treatment: 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>

