



Do you have bladder cancer that has spread to the lymph nodes?

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

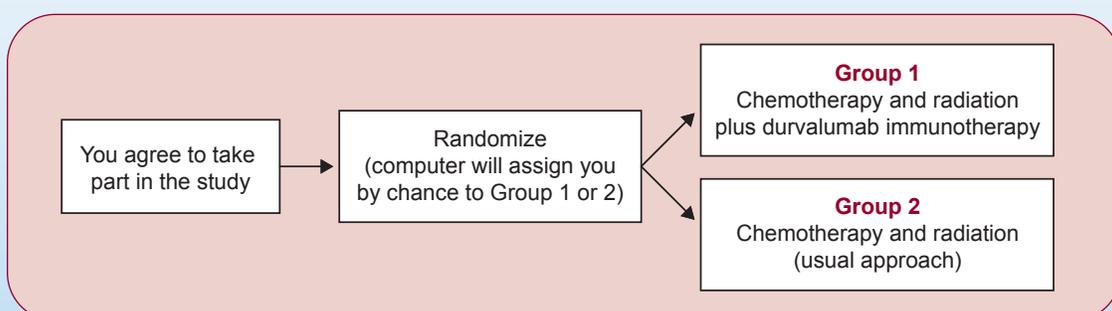
A Study of Chemotherapy and Radiation Therapy Compared to Chemotherapy and Radiation Therapy plus Durvalumab Immunotherapy for Bladder Cancer which has Spread to the Lymph Nodes

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new drugs and approaches for treating bladder cancer.
- All study participants will receive the usual treatment for this cancer, which is chemotherapy and radiation. Some study participants will also receive an immunotherapy treatment, durvalumab, by vein (intravenously).
- The purpose of the EA8185/INSPIRE study is to compare the usual treatment (chemotherapy and radiation) with adding durvalumab immunotherapy to chemotherapy and radiation, in order to find out which treatment approach is better.
 - The study doctors will look at the frequency with which the tumor completely disappears after treatment with durvalumab compared to the usual approach.

WHAT does this study involve?

- If you decide to participate in EA8185/INSPIRE, you will be assigned by chance (randomized) to one of the two groups listed below. You may or may not have completed chemotherapy (per your doctor's choice) prior to being assigned to one of these groups. However, if you did receive chemotherapy prior to being assigned to one of these groups, your bladder cancer must not have worsened.
 - **Group 1**—chemotherapy chosen by your doctor, and radiation (5 days a week) for 6.5–8 weeks, in addition to durvalumab immunotherapy for 3 doses (given once every 21 days by vein)
 - **Group 2**—chemotherapy chosen by your doctor, and radiation (5 days a week) for 6.5–8 weeks



- After study treatment is completed, you will have exams such as CT scan or MRI of your belly to take pictures of your bladder that will allow your doctor to see if your cancer has responded to treatment.
 - If you are in Group 1 and the bladder cancer has shrunk, gone away, or remained stable, you will be offered more treatments with durvalumab alone for up to 6 months.
 - If you are in Group 2 and your cancer has shrunk, gone away, or remained stable, you will be watched closely without any additional chemotherapy and radiation treatment. In special circumstances (if you did not get any chemotherapy prior to the chemotherapy and radiation you receive for EA8185/INSPIRE), more chemotherapy is allowed if your physician recommends it.
 - If your cancer has not shrunk, gone away, or remained stable, your doctor may offer you surgery or some other treatment.
- After you finish your treatment, your doctor and study team will monitor you for up to 3 years.
 - This will consist of visits to the doctor's office and CT scans of the bladder every 3 months for 1 year, every 6 months in the 2nd year, then once a year in the 3rd and 4th year.
 - In addition, your urologist will also follow you with cystoscopy (to look at your bladder) every 3 months for 2 years, then every 6 months until year 3.
 - If you are in Group 1, you will also have monthly check ups with your doctor for up to 6 months.

WHO will take part in this study?

- Approximately 95 people will take part in EA8185/INSPIRE.
- Participants must be at least 18 years old, and must not have had previous radiation therapy to the pelvic area.
- Please note, 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 some or all of the costs of medical care you get as part of this study.
- You/your insurance provider will **not** have to pay for durvalumab while you take part in this study. However, you/your insurance provider will have to pay for the costs of preparing and administering durvalumab.
- Check with your insurance company to find out what they will pay for.

IF you would like to know more

- About the EA8185/INSPIRE study, talk with your doctor, or:
 - Visit www.ecog-acrin.org and search EA8185, then select the link to the EA8185 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: 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>

