

Treatment Visit

Receiving Avelumab Through an IV



What is it?

Avelumab is given through a vein using an IV infusion. A small tube is placed into a vein, usually in the arm, and the medicine slowly enters the bloodstream.



Why is it needed?

Avelumab is the study treatment for patients assigned to the avelumab plus best supportive care group. It is an immunotherapy designed to help the immune system recognize and fight cancer cells.



How often does it happen?

Avelumab is given as a 1-hour IV infusion once every 2 weeks at a dose based on body weight.



How to prepare?

Wear comfortable clothing with sleeves that can be rolled up. Bring your medication list. Tell the study team if you have fever, chills, rash, breathing problems, chest discomfort, dizziness, or any new symptoms before the infusion starts.



What you may feel?

You may feel a small pinch when the IV is placed. During the infusion, some patients may feel chills, fever, flushing, itching, dizziness, shortness of breath, or back discomfort. The study team monitors for infusion-related reactions and may slow or stop the infusion if needed.



How long it takes?

The infusion itself takes about 1 hour. The full visit may take longer because of check-in, vital signs, blood tests, premedication, and observation.



What happens afterward?

The team may check how you feel before you leave. Call the study team right away if you develop trouble breathing, swelling, rash, fever, chills, chest pain, severe dizziness, or symptoms that worry you.



Key takeaway: This visit gives the study medicine and helps the care team make sure you are tolerating treatment safely.

Ask your study team what to expect before your first infusion and what symptoms should be reported after you leave.

Cancer Monitoring

CT/MRI Scans to Check the Cancer



What is it?

CT and MRI scans take detailed pictures inside the body. In this study, they are used to check known cancer areas and look for changes over time.



Why is it needed?

Scans help the study team see whether the cancer is stable, shrinking, or growing. The protocol uses radiological tumor assessments based on RECIST v1.1, a standard method for measuring tumors in clinical trials.



How often does it happen?

The protocol requires a scan within 28 days before randomization to confirm eligibility. After randomization, scans are done at 8 weeks, then every 8 weeks for the first year, and every 12 weeks afterward until disease progression.



How to prepare?

Ask whether contrast dye will be used. Tell the team if you have kidney problems, contrast allergy, implanted devices, metal in your body, claustrophobia, or trouble lying flat



What you may feel?

For a CT scan, you lie on a table that moves through the scanner. If contrast is used, you may feel warmth or a metallic taste. For an MRI, you lie still inside a scanner that makes loud tapping sounds.



How long it takes?

A CT scan may take about 10–30 minutes. An MRI may take 30–60 minutes, depending on the area scanned.



What happens afterward?

You can usually return to normal activities. The study team compares the new scan with previous scans and reviews whether the cancer has changed.



Key takeaway: These scans help the study team track whether the cancer is stable, shrinking, or growing.

Ask your study team what to expect before your first scan and what symptoms should be reported after you leave.

Tumor Tissue Testing

A sample used to study cancer biomarkers



What is it?

A tumor tissue sample is a small piece of tumor that can be studied in a lab. The study may use a recent stored tumor sample. If a suitable sample is not available, a new biopsy may be needed before joining the study.



Why is it needed?

Tumor tissue helps researchers study biomarkers that may be linked to treatment response. In this study, examples include PD-L1 expression and tumor-infiltrating CD8+ T cells.



What does the study collect?

The study requires a recent tumor tissue sample. It may also use archived tissue if available. A new biopsy may be collected in some situations if medically appropriate.



How to prepare?

Preparation depends on where the biopsy is taken. The team may review medications, blood thinners, allergies, imaging needs, and whether someone should drive you home.



How is it performed?

If a new biopsy is needed, the doctor uses imaging or exam guidance to collect a small tissue sample. The area is cleaned and numbed first. The exact method depends on where the tumor is located. The biopsy may take about 30–90 minutes.



What you may feel?

You may feel pressure or a brief pinch from numbing medicine. You should not feel sharp pain. Tell the team if you feel pain or need a break.



What happens afterward?

The site may be covered with a bandage. You may be asked to avoid heavy activity for a short time. Call the team for fever, worsening pain, bleeding, swelling, or breathing trouble.



Key takeaway: This sample helps researchers understand the cancer biology and why patients may respond differently.

Ask your study team whether existing tumor tissue can be used or whether a new biopsy is needed.

Heart Safety Blood Test

A blood test that helps check for signs of heart inflammation



What is it?

Troponin is a blood test that can show if the heart muscle is irritated or injured.



Why is it needed?

Avelumab and other checkpoint inhibitors can rarely affect the heart. This test helps the study team look for early signs of heart inflammation, called myocarditis. The protocol includes troponin testing during early study visits and when clinically needed.



How to prepare?

No special preparation is usually needed. Tell the team right away if you have chest pain, shortness of breath, fast heartbeat, fainting, swelling, unusual fatigue, or dizziness.



What you may feel?

This feels like a regular blood draw. You may feel a quick pinch.



How long it takes?

The blood draw takes only a few minutes. Results may take longer, depending on the clinic.



What happens afterward?

The study team reviews the result. If something looks abnormal, they may repeat the test, order more heart checks, pause treatment, or send you for urgent care.



Key takeaway: This blood test helps the team watch for rare heart-related side effects early.

Ask your study team what to expect before your first infusion and what symptoms should be reported after you leave.

Symptoms & Daily Life Questionnaires

Your answers help show how treatment affects daily life



What is it?

These are short forms that ask about your symptoms, daily activities, and overall health.



Why is it needed?

Scans and lab tests do not show everything. These questionnaires help researchers understand how patients feel and function during the study.



What forms are used?

The protocol includes NCCN-FACT FBISI-18 and EQ-5D-5L questionnaires to assess bladder cancer symptoms, functioning, quality of life, and overall health status.



How to prepare?

Think about how you have felt recently. Answer honestly based on your own experience. There are no right or wrong answers.



What you may feel?

Some questions may feel personal or emotional. You can ask for help understanding a question, but the answers should reflect how you feel.



How long it takes?

Usually about 5–15 minutes, depending on the number of forms.



What happens afterward?

Your answers are recorded as part of the study. They may help the team notice symptoms and help researchers evaluate the patient experience.



Key takeaway: Your voice matters. These forms measure how treatment affects daily life, not only scan results.



Safety Monitoring

Blood Tests to Check Your Safety



What is it?

Routine blood tests use a small needle to collect blood from a vein. The sample is sent to a laboratory.



Why is it needed?

Blood tests help the study team monitor your safety. They can show how your blood counts, liver, kidneys, thyroid, hormones, and other body systems are doing during the study.



What does the study check?

The protocol includes blood testing for hematology, blood chemistry, coagulation, thyroid function, ACTH, troponin, pharmacokinetics, anti-drug antibodies, and research biomarkers. Safety is monitored through laboratory tests and clinical visits during the study.



How to prepare?

Drink water unless the team gives different instructions. Ask whether fasting is needed. Tell the team if you bruise easily, take blood thinners, or have felt faint during blood draws before.



What you may feel?

You may feel a quick pinch or pressure. Some people feel lightheaded. A small bruise can happen afterward.



How long it takes?

The blood draw usually takes only a few minutes. Some visits may take longer if several blood samples are needed.



What happens afterward?

A bandage is placed on the site. The study team reviews results to decide whether it is safe to continue treatment or whether more evaluation is needed.



Key takeaway: Blood tests help the study team catch safety changes early and decide whether it is safe to continue treatment.

Ask your study team if you need to fast, if you take blood thinners, or if you have fainted during blood draws before.