

# Study Design: What treatment could I receive and what happens next?

Maintenance treatment after first-line platinum chemotherapy for locally advanced or metastatic urothelial cancer

## STEP 1 — STARTING POINT 1 Before Joining the Study

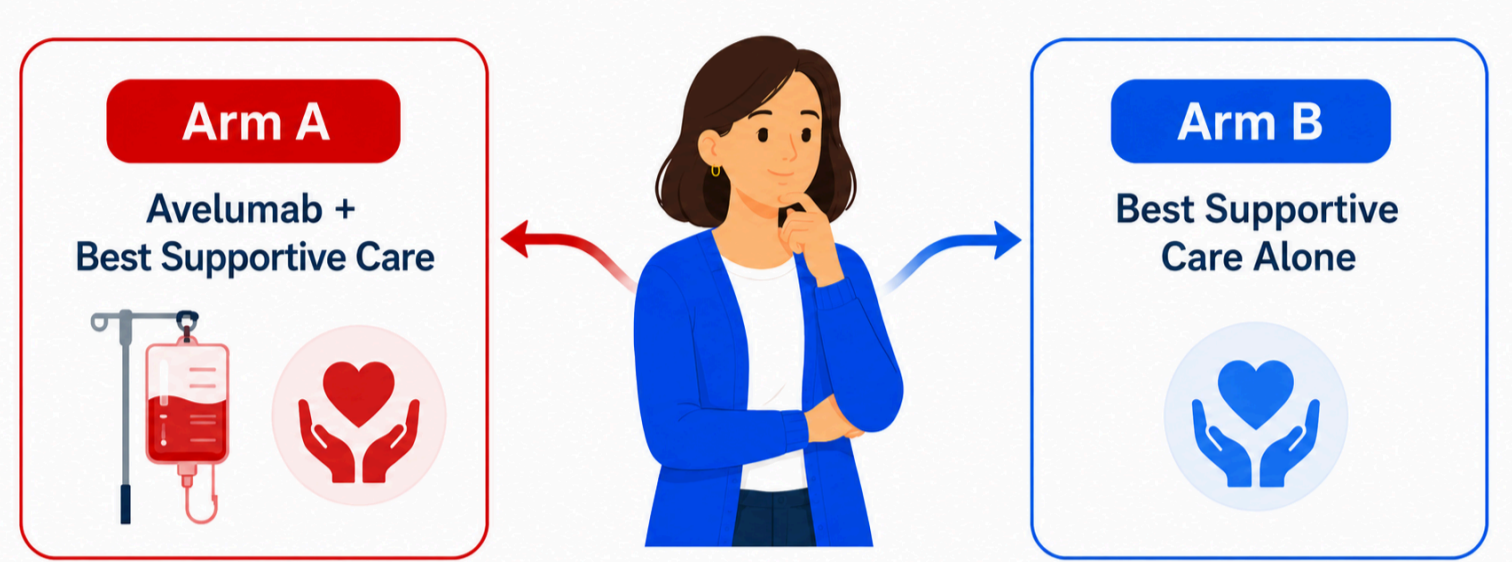


Patients may enter this study if they:

- Have locally advanced or metastatic urothelial cancer
- Already completed 4–6 cycles of first-line platinum-containing chemotherapy
- Had no disease progression after chemotherapy (complete response, partial response, or stable disease). A confirmatory CT or MRI scan is done within 28 days before randomization

This study is for patients whose cancer is controlled after chemotherapy and who may receive maintenance treatment.

## STEP 2 — ASSIGNMENT 2 Randomization — Assigned by chance to 1 of 2 groups



1:1

Each patient has an equal chance of being assigned to either group

Neither the patient nor the doctor chooses the group. The study assignment is made randomly.

### ARM A

Avelumab + Best Supportive Care

#### WHAT THE PATIENT RECEIVES

- Avelumab by IV infusion
- Dose: 10 mg/kg
- Schedule: every 2 weeks
- Infusion time: about 1 hour

### ARM B

Best Supportive Care Alone

#### WHAT THE PATIENT RECEIVES

- No avelumab at the start
- No active anti-cancer study drug
- Best supportive care as needed

#### BEST SUPPORTIVE CARE MAY INCLUDE:

- Symptom management
- Pain control
- Antibiotics if needed
- Nutritional support
- Supportive medical care as needed

Premedication may be given before infusions to help reduce infusion-related reactions.

This group does not receive active anti-cancer maintenance treatment at the start of the study.

## STEP 3 — ONGOING 3 What Happens During the Study?



#### TUMOR SCANS

- At 8 weeks after randomization
- Then every 8 weeks for the first year
- Then every 12 weeks after that

#### THE STUDY TEAM CHECKS

- Blood tests, symptoms, and general health
- Side effects and medications
- Whether cancer stays stable, shrinks, or grows

These checks help the team understand how the patient is doing and whether treatment should continue.

## STEP 4 — POSSIBLE PATHS 4 What Could Happen During the Study?



#### Treatment continues

Cancer is controlled and side effects are manageable — patient stays in their assigned group.



#### Treatment stops

Cancer gets worse, side effects are too severe, or the patient or doctor decides to stop.

Arm A only — Avelumab may continue after progression if the doctor believes there is still clinical benefit.



#### Arm B patients may switch

Patients on best supportive care alone may later be offered avelumab + best supportive care if they meet study requirements.

## STEP 5 — AFTER TREATMENT 5 Follow-Up After Study Treatment Ends



#### THE STUDY TEAM MAY CONTINUE TO CHECK:

- Survival status
- General health
- New cancer treatments
- Safety information

#### FOLLOW-UP MAY HAPPEN:

- At clinic visits
- By phone contact
- About every 3 months for long-term follow-up

#### KEY TAKEAWAY

After first-line chemotherapy, eligible patients are assigned by chance to either **Avelumab + Best Supportive Care** or **Best Supportive Care alone**, then followed with regular scans, safety checks, and long-term follow-up.

For informational purposes only. Refer to the full protocol and your study team for complete eligibility and treatment details.



### Study Team Contact

When in doubt, call your study team

Daytime phone:

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After-hours:

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