

Thank you
for your interest
in the ABLE-32 study
for adults with
intermediate risk
NMIBC.

For more information, please visit
ABLEclinicalstudies.Ferring.com/able32/,
scan the QR code below, or contact:

[Study site contact information]



Committed to hope.
Dedicated to patient lives.
The future of bladder
cancer research
is here.



Ask your doctor if you are eligible for the
ABLE-32 clinical research study.

What is a clinical study?

A clinical study is a research study involving volunteers (also called participants) that is intended to add to medical knowledge of a disease or condition, in this case, bladder cancer.

What is a study drug?

A study drug contains a substance that is being tested in clinical studies. Every study drug is reviewed by a government health authority, such as the United States Food and Drug Administration (FDA), and an ethics committee for testing in people.

Why is the ABLE-32 study important?

No treatments for intermediate risk, non-muscle invasive bladder cancer (NMIBC) are currently approved by the FDA or any other health authority.

This study is evaluating an investigational study drug called nadofaragene firadenovec in adults with intermediate risk NMIBC. Nadofaragene firadenovec is currently approved by the United States FDA under the tradename ADSTILADRIN® for the treatment of high risk NMIBC that has not responded to BCG treatment. Clinical studies like this one aim to find new and better ways of preventing, diagnosing, and treating the disease. Being part of discovering new health information may help others in the future.

What is the purpose of this study?

This study is evaluating nadofaragene firadenovec to find out how effective and tolerable it is in preventing intermediate risk NMIBC from returning after removal.

Who can participate in the ABLE-32 study?

To be eligible for this study, you must:

- Be at least 18 years of age
- Be diagnosed with intermediate risk NMIBC

This is not a complete list of study requirements. The study doctor will review the full requirements with you.

How long will this study last?

You will be in this study for up to 5 years, which includes a study treatment period (up to 2 years) and a follow-up period (3 years).

What can I expect if I decide to participate?

If you are eligible to participate, your study doctor will first perform a transurethral resection of bladder tumor (TURBT) to remove the tissue from your bladder that could be cancer. After this procedure, you will be randomly assigned to 1 of the following groups (arms) during the study:

Arm 1:	Arm 2:
receive nadofaragene firadenovec (study drug)	observation (no study drug; standard treatment)

Arm 1 participants will receive the study drug once every 3 months at the clinic visits during the 2-year study treatment period unless the cancer returns. The study drug will be given directly into the bladder through a urinary catheter.

Arm 2 participants will come to the clinic twice every 3 months during the first 2 years and will be provided standard treatment. If you are in Arm 2 and if your cancer returns within the first 2 years, you will be given the option of receiving the study drug once every 3 months at clinic visits for up to 2 years.

Laboratory tests, cystoscopy (procedure to examine the bladder and urethra), heart tests, bladder biopsies, and other assessments and questionnaires will be conducted as part of this study.

What are the costs to take part in this study?

You will receive all study-related procedures and the study drug at no cost. Certain participants may also be eligible for compensation for study-related travel expenses.

What risks are involved for study participants?

There are possible risks involved with any clinical study. The research staff will review the risks with you, and you will be closely checked by the research staff throughout the clinical study.

Why should I take part in this study?

Participation in a clinical study is voluntary. Clinical studies are important for medical advances. By participating in the study, you may:

- Have your health and condition closely checked through regular visits with your study doctor
- Be a part of discovering new health information that may help others in the future