MoonRISe-1 is a clinical research study of an investigational drug delivery system for adults with intermediate-risk non-muscle invasive bladder cancer.

MoonRISe-1

MoonRISe-1 Study Overview

The MoonRISe-1 study is evaluating an investigational drug delivery system called TAR-210. Study doctors want to learn more about the effects of TAR-210 when it delivers controlled doses of an investigational medication (erdafitinib) into the bladder over approximately 12 weeks. TAR-210 is not approved for use by any regulatory authority and can only be used in research studies such as this one.

Participation in this study could last up to 5 years and is divided into 3 phases:

Screening (lasts about 3 months)

Your decision to begin screening is voluntary and will not affect your medical care.

- You'll be asked to sign the informed consent form (ICF) to begin
- Screening may take place over multiple visits during the 3-month period to determine if you meet the study requirements
- You will not receive any study medication during this time

Screening will also include testing your tumor for specific genetic alterations called fibroblast growth factor receptor (FGFR) alterations. FGFR alterations can be a factor in tumor growth and whether the cancer spreads.

To learn whether your tumor has FGFR alterations, FGFR testing needs to be performed on a urine and/or tumor tissue sample collected at screening. If your tumor has the required FGFR alterations, you may be eligible to participate in the MoonRISe-1 study.

Study Treatment Period (lasts about 1 year)

If you are eligible for this study, you will be randomly assigned (like the flip of a coin) to Group A or Group B. You have an equal chance of being in either study group.

Group A: The investigational drug delivery system (TAR-210)

- TAR-210 will be inserted into the bladder and remain there for 12 weeks at a time
- Every 12 weeks, TAR-210 will be removed and a new one will be inserted
- You will have approximately 6 study clinic visits during which your health will be evaluated. Additional assessments to check if your bladder cancer has returned or become worse may also be performed through various health exams and tests.
    - At 5 of these visits, you will have TAR-210 inserted/removed

Group B: Standard of Care Chemotherapy (intravesical Mitomycin C or Gemcitabine)

- The study doctor will decide which chemotherapy you will receive, and it will be administered directly into the bladder
- For the first 4-6 weeks, you will receive a weekly dose (4 to 6 total doses)
- After 4-6 weeks, you will receive regular doses based on standard of care (approximately every month for at least 6 months and up to 1 year). The study doctor/staff will talk with you more about this.
- Aside from your dosing visits, you may have clinic visits during which your health will be evaluated. Additional assessments to check if your bladder cancer has returned or become worse may also be performed through various health exams and tests.

Follow-Up (lasts up to 4 years)

- You will have the first follow-up visit about 30 days after you complete the Study Treatment Period
    - After that visit, you will have follow-up visits every 12-24 weeks

About the Investigational Drug Delivery System (TAR-210)

The investigational drug delivery system (TAR-210) is a small, flexible tube that is inserted into the bladder by a healthcare professional using a urinary catheter. TAR-210 is designed to remain in the bladder and to release a controlled amount of the investigational medication directly into the bladder for approximately 12 weeks after insertion.

The investigational drug delivery system will then be removed with a cystoscope and replaced with another TAR-210 by a healthcare professional.

Potential Side Effects of the Investigational Drug Delivery System

All study medications have side effects, some of which are more serious than others. Not all side effects related to TAR-210 are known at this time. The most common side effects reported are similar to those seen after routine urologic procedures such as:

- Symptoms of bladder irritation (urgency, frequency, pain)
- Blood in the urine
- Cystitis (bladder inflammation)
- Urinary tract infection
- Urinary incontinence
- Discomfort

Please refer to the ICF to review the full list of possible side effects of the investigational drug delivery system and study medications.

Key Study Health Exams and Tests

During your study clinic visits, you will have various health exams and tests, which might include:

- Vital signs measurements to check your temperature, weight, pulse/heart rate, and blood pressure
- Physical exam to check your general health
- Questionnaires about how you are feeling
- Urine sample to check your overall health, for pregnancy (if applicable), and how your body reacts to the study medication
- Ultrasound to evaluate your bladder and kidneys
- CT/MRI scans of your body to check the status of your disease
- Blood draw to check your general health, the effect of your study medication, for pregnancy (if applicable), and for signs of infection
- Cystoscopy, a type of procedure where the study doctor will use a cystoscope which is a hollow tube with a camera to examine the inside of your bladder
- TURBT (transurethral resection of bladder tumor) procedure to remove tumor tissue

General Study Information

- All study-required visits, tests, and medication will be provided at no cost to you
  - You may also be reimbursed for study-required travel or expenses
- Participation in this study is voluntary, and you can choose to stop participating at any time and for any reason

If you have questions about this study or want to learn more about how you could participate, please contact:

Site Contact Details

Approved by Sterling IRB, IRB ID: 11652

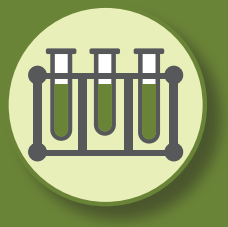
FGFR Alteration Testing in Clinical Research Studies

You could be eligible for a clinical research study for patients who have a specific change in one or more genes called fibroblast growth factor receptors (FGFRs). The purpose of this flyer is to help you understand more about FGFR alterations, as well as why and how testing for FGFR alterations occurs.

What is an FGFR alteration?

FGFR is a protein found in cells that helps the cells grow and multiply. When a mutation or change occurs in FGFR genes, it is known as an FGFR alteration. FGFR alterations may lead to the development and growth of bladder cancer cells.

How is FGFR testing performed?



To test for FGFR alterations, biological samples of urine and/or tumor tissue must be collected. These samples are then tested for the presence of FGFR alterations in a lab.

Why is FGFR testing important?

Testing for FGFR alterations in a bladder tumor helps doctors and patients know more about the tumor. If your tumor has an FGFR alteration, you may be eligible for a clinical research study.

The study doctor or a member of the study staff can talk with you about your bladder cancer, FGFR alterations, and study eligibility in more detail.

Questions

If you have questions about this flyer or FGFR alterations, please speak with the study doctor or a study staff member. If you would like to learn more about or search for a clinical research study, please visit globaltrialfinder.janssen.com.

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