How long will I be in the ENACT study?

Your participation will last for at least 2 years with the potential for up to 3 years depending upon when you are enrolled in the study. During the first 2-year period, you will return for visits to your study doctor every 3 months. You may then be followed for up to an additional year, during which time, you will return to see your study doctor every 6 months.

What else do I need to know?

If you are admitted to the study, you will be randomly assigned to receive enzalutamide or continue with active surveillance (AS). You have a 50% chance of being assigned to either group.

If you are placed in the enzalutamide group, you will take 4 capsules daily by mouth for 1 year.

Who can I speak with about the ENACT study?

To learn if the ENACT study is right for you or your loved one, please contact an ENACT study representative at:

astellas

ENACT active surveillance

Master_ENACT Study Patient FAQ Brochure_9785-MA-1010_v0c_US_21Nov2016

DON'T WANT TO WAIT?

If you want to do more than actively monitor your prostate cancer, the ENACT clinical research study may be right for you.

ENACT active surveillance

What is the ENACT clinical research study?

It is common for doctors to place prostate cancer patients with early-stage and less aggressive cancer on an active surveillance (AS) plan. In AS, the cancer is not actively treated but is instead carefully watched. If the cancer does start to progress, the patient will stop AS and will start active treatment. Often, the reason men and their doctors choose AS is to avoid, for as long as is reasonably possible, the side effects of prostate cancer treatment.

The ENACT study is evaluating whether a medication called enzalutamide can prolong the amount of time before active treatment for prostate cancer (such as radiation or surgery) becomes necessary. Enzalutamide is already approved by the FDA as a medication for later stage prostate cancer.

Why should I participate in the ENACT study?

A clinical research study is a carefully designed scientific evaluation of a drug or treatment conducted by doctors. Today's treatments exist mainly because of the people like you who have volunteered to participate in past clinical studies.

By taking part in the ENACT study, you are helping researchers discover potential new treatments that could change the future of how we manage early stage, localized prostate cancer. The current options for men with early stage, localized prostate cancer are either AS or active treatments which have sexual and urinary side effects. More research is needed to develop additional options for men with early stage, localized prostate cancer.

Although the drug being studied in ENACT (enzalutamide) is an investigational drug for men with early stage, localized prostate cancer, enzalutamide is approved in the United States and Canada to be used in patients with later stage prostate cancer. It has been used by over 140,000 prostate cancer patients worldwide since 2012.

How do I join the ENACT study?

To participate in ENACT, you must:

- Have been diagnosed with localized prostate cancer within the last 6 months
  - This is limited to low- or intermediate-risk prostate cancer (according to NCCN guidelines), ask your doctor if this matches your diagnosis
- Have prostate cancer that has NOT spread beyond the prostate gland
- Currently be undergoing active surveillance (AS) only
- Have NOT received prior therapies or surgeries for your prostate cancer
- Be able to swallow pills and be willing to comply with the study requirements

In addition to the above requirements, there are certain medications and medical conditions that can disqualify you from participating in ENACT. Your doctor will check your medications and medical history before you can join the study.

What can I expect during my study visits?

If you are eligible and decide to participate in the ENACT study, with your permission, certain procedures will be conducted at every visit, while others will only be conducted some of the time. The procedures done during ENACT study visits are commonly done for patients on AS. All procedures done because of your participation in the ENACT study will be done at no cost to you.

At every visit you will:

- Have a physical exam
- Have your weight, blood pressure and pulse measured
- Be asked questions about your general health, complaints or side effects, and any additional medications you are taking
- Have routine blood tests, including one to determine your PSA level

Other procedures will be done on occasion or as needed, including:

- Digital rectal exam (scheduled for once every 6 months)
- Urine sample collection (scheduled for once every 6 months)
- Prostate biopsy (scheduled for once every 12 months)
- ECG (to measure your heart's electrical activity; scheduled to occur once)
- Patient-completed Questionnaires (scheduled to occur every 6 months, with one additional brief questionnaire completed 3 months after you start the study)

ENACT
active surveillance