



CLINICAL TRIAL OPTIONS

For Men With
Prostate Cancer

ZERO 
THE END OF PROSTATE CANCER

Is a Clinical Trial Right for You?

Nearly 2.9 million American men are living with prostate cancer. If you are one of them, you may be exploring treatment possibilities, or you may not know what to do from here. Joining a clinical trial may be one of your options. Hundreds of thousands of people have participated in clinical trials, testing new drugs that are now available. There is hope; you are not alone.

Clinical trials (also called clinical studies) are scientific research to further medical advancements and refinements. Clinical trials provide critical data needed to submit new therapies to the Food and Drug Administration (FDA), the government agency that determines if treatments can be prescribed to fight a disease, such as prostate cancer.

Clinical trials help:

- Determine if an experimental therapy is safe and if it works better than existing alternatives
- Study the effects of potential treatments
- Gather scientific evidence for future patient care



You may consider a clinical trial for several reasons:

- Try new treatments that aren't yet available
- Have frequent monitoring
- Benefit from expert medical care
- Play an active role in your health care decisions
- Help others by contributing to the development of future treatments

People who participate in clinical studies are volunteers, and they are always free to withdraw from a trial at any time and for any reason. Some clinical trials have a single group of patients that only receive the experimental treatment. Others have two groups of patients that receive different treatments depending on what group they are in. One group of participants receives the experimental treatment, and the second group of participants are given either another treatment or a placebo which has no direct therapeutic effect. It's important to know that placebos are not typically used in prostate cancer studies, unless no treatment is currently available.

As a prostate cancer patient, you should know that many clinical trials address both therapeutic efficacy and quality of life.

Clinical trials typically compare new medical approaches to standard, available treatments and explore ways to help people who have chronic diseases cope with their medical conditions.

What's Meant by Clinical Trial Phases?

Most treatment studies progress along a four-phase path determined by the FDA to protect study volunteers, while answering questions about a new therapy's safety and use.

PHASE 1 TRIALS

An experimental therapy is given to a small group of patients for the first time to determine drug safety, side effects, and dose.

PHASE 2 TRIALS

An experimental therapy is given to a larger group of patients to explore the efficacy of treatments.

PHASE 3 TRIALS

An experimental therapy is given to an even larger group of patients to compare a treatment to the current standard of care and to assess its effectiveness and side effects.

PHASE 4 TRIALS

After a treatment has been approved by the FDA, the study continues to track side effects and optimal use over a longer period of time with a broader unselected population.

What Should You Consider Before Joining a Clinical Trial?

To help determine if a clinical trial is right for you, it is important to explore and discuss these factors with your family and health care team.

- **Insurance:** A majority of insurance policies cover standard treatments that are included in the care of patients on clinical trials, and are not a barrier to clinical trial participation.
- **Benefits and risks:** You need to feel comfortable knowing that the investigators do not know whether the treatment being studied is better suited for you than your other options. This is the essence of why researchers must study new treatment regimens.
- **Safety/protection:** After speaking with the study team and exploring all elements of the study, do you understand the safety risks associated with the drug and study participation? Do you feel safe? Are you confident that you will be protected while participating in this study?
- **Preparations:** Study participation often brings with it complex information, and a lot of it. You may find it helpful to prepare an ongoing list of questions for your study team. Many people also bring a friend or relative to take notes and/or record study appointments to help ensure understanding and to capture important information.



Information
is key to making
educated treatment decisions.

A Checklist of Questions to Ask



Whether you're considering volunteering for a clinical study or if you've already decided, it's important to communicate clearly and often with your health care team. Make sure you understand all elements of the study. Speak up if you're uncomfortable or unsure of anything related to your care or choices. Develop good relationships with the study staff, urologist, oncologist, and nurse. And most importantly, feel empowered to ask any and all questions related to your care. Some of these might include:

- Are study costs covered?
- Will my study-related travel and expenses be reimbursed?
- Will taking part in the trial impact my ability to take certain treatments in the future?
 - If so, which treatments?
- Will the results of the study be published?
- What data will you be collecting?
- Will you keep me informed about what's going on with the study?
- Were patients and/or caregivers involved in the design of the study?
- How much time will the study require?
 - What is the duration of the study?
 - What should I anticipate about study visits and monitoring?
 - What types of exams and tests will be necessary?
 - Will I be monitored even after I stop taking the study drug? If yes, how long?
- What is the goal of this study?

Understanding clinical studies will help you better consider all of your options.



- What do we know about the experimental treatment?
 - What were the results of earlier studies?
 - What side effects might I experience?
 - How does the experimental therapy work?
 - Will the treatment benefit me?
- How long do I have to decide if I want to participate in the study?
- Can I speak with patients who are now in the study?
- What if I want to stop participating in the study?
- Can I remain on the treatment if it's working, even after the study ends?



*Interested in more clinical trials information including videos and webinars? **Visit [zerocancer.org](https://www.zerocancer.org).***

What Terms Might You Encounter?

Clinical research has its own vocabulary, which can feel intimidating and overwhelming. The following glossary will help you familiarize yourself with frequently used words and terminology in discussions with your health care team.

- **Adverse event/reaction** - A negative change in the health of a study participant during or after the study. Adverse events and side effects are closely monitored, as they may be related to study treatment.
- **Control** - The standard by which an experimental therapy is measured or compared, usually to another medicine. A control arm helps determine the impact of experimental medication.
- **Double blind** - A study in which neither the health care team nor the patient knows the treatment arm assigned. This arrangement is meant to reduce the risk of bias and to prevent the influence of results. Double blinding helps to ensure objective observation, so study results are more likely to be valid and reliable.
- **Inclusion/exclusion (I/E) criteria** - A specific list of requirements, guidelines or traits that determine who can or cannot participate in a study. Typically included are age, type and stage of disease, prior treatments, other medical conditions, and current medications.
- **Informed consent** - The process of sharing detailed study information with potential participants to help them decide if they want to join the study. Informed consent includes information on possible risks and benefits associated with the treatment itself as well as trial participation. This information helps patients know what to expect, and continues throughout the course of the study.
- **Institutional Review Board (IRB)** - An independent team that protects trial participants by reviewing, approving, and monitoring clinical studies on a medical, ethical, and legal basis.
- **Open label** - Typically a Phase 1 or Phase 2 study in which everyone – health care team and patient – is aware of the assigned treatment. An open label study is the opposite of a double blind study (see Double Blind).
- **Protocol** - A detailed written research plan that includes the reason for study, who can participate, number of participants and information to be gathered about them, study length, schedule for treatments and tests involved. Study protocols must be approved by IRBs (see above) before patients can join.
- **Placebo** - A mock treatment or substance that looks and is given like study treatment, but has no active ingredients. It's important to know that placebos are not typically used in cancer studies, unless no treatment is currently available.
- **Randomization** - How different treatments choices are assigned without bias, like flipping a coin.
- **Regulation** - Federal agencies oversee all medical research and clinical studies. These include the FDA and the National Institutes of Health (NIH).
- **Sponsor** - The study funder, initiator, and/or authority. Typical study sponsors are pharmaceutical companies, academic institutions, physicians, volunteer groups, and federal government agencies.
- **Standard of care** - The typically used, best available treatment. Often the standard of care is the control of a clinical trial (see above).
- **Study arm** - The group to which a trial participant is assigned.

Introducing the TRITON Trials

TRITON2 is a **Phase 2** clinical trial now enrolling patients. Conducted by Clovis Oncology, this study is exploring rucaparib, a new potential treatment. Rucaparib is an oral tablet that has been shown to kill cancer cells with certain genetic mutations or alterations.

What is the goal of TRITON2? The purpose of this study is to determine the impact of rucaparib on metastatic prostate cancer that has worsened despite having received treatment with chemotherapy and hormonal therapy.

Eligibility Requirements:

- You have progressing metastatic, castration resistant prostate cancer.
- You have already been treated with Zytiga, and/or Xtandi, and some chemotherapy.
- You have tumors with mutations or alterations in BRCA1, BRCA2, or ATM, or other genes related to DNA repair.

For more information on the **TRITON2 Clinical Trial** and how to participate, speak with your doctor and go to <http://www.tritontrials.com> or call 855-262-3040.

TRITON3 is a **Phase 3** clinical trial now enrolling patients. Conducted by Clovis Oncology, this study is also exploring rucaparib, specifically its impact compared to several other therapies that are used to treat metastatic, castration-resistant prostate cancer.

What is the goal of TRITON3? The goal of this study is to compare the effect of rucaparib with the effect of Zytiga, Xtandi, or Taxotere.

Eligibility Requirements:

- You have tumors that have BRCA1, BRCA2, or ATM genetic mutations or alterations.
- You have already been treated with Zytiga, Xtandi, or Erleada and have not yet received chemotherapy for prostate cancer.

For more information on the **TRITON3 Clinical Trial** and how to participate, speak with your doctor and go to <http://www.tritontrials.com> or call 855-262-3040.

SUPPORT FOR PROSTATE CANCER PATIENTS

You are not alone in your prostate cancer journey. ZERO offers the following patient support to help you along the way. These programs are offered at no cost to you.

ZERO360: Comprehensive Patient Support

zerocancer.org/zero360 Our team of experienced case managers is ready to help you and your family through your personal prostate cancer journey. ZERO360 is a free, comprehensive patient support service to help patients and their families navigate insurance and financial obstacles to cover treatment and other critical needs associated with cancer. **1-844-244-1309 (Toll-Free)**

MENtor: Peer Support

zerocancer.org/mentor MENtor is a support network for newly diagnosed men living with prostate cancer, as well as men who have experienced a recurrence. Our trained, volunteer MENtors represent many different prostate cancer journeys and have a wealth of insights to share based on their experiences.

Prostate Cancer Support Network: ZERO Connect

[facebook.com/groups/zeroconnect](https://www.facebook.com/groups/zeroconnect) ZERO Connect is a Facebook-based, support group where those affected by prostate cancer can share their stories, ask questions, and connect with one another on their prostate cancer journey. It is a community of prostate cancer patients, survivors, caregivers, family members, loved ones, and friends who come together to support one another.



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