CURA LOCATIONS

ANNE ARUNDEL COUNTY
Hanover
7580 Buckingham Blvd., Suite 100
Hanover, MD 21076
410-760-9400

BALTIMORE COUNTY
Greater Baltimore Medical Center (GBMC)
Physicians Pavilion North
6535 North Charles St., Suite 625
Towson, MD 21204
410-825-5454

Towson/Ruxton Professional Center
8322 Bellona Ave., Suite 202
Towson, MD 21204
410-825-6310

White Marsh/Franklin Square
6820 Hospital Drive, Suite 210
Baltimore, MD 21237
410-391-6131

Owings Mills/Continence Center
21 Crossroads Drive, Suite 200
Owings Mills, MD 21117
410-581-8140

Owings Mills/Prostate Center
2 Park Center Court, Suite A
Owings Mills, MD 21117
443-738-9393

CLINICAL TRIALS
TOMORROW’S TREATMENT TODAY

A Guide to Clinical Trials
What are clinical trials?

A clinical trial is a carefully designed research study that investigates the effectiveness of a specific treatment for a particular group of people. Well-designed clinical trials are the fastest way to find treatments that work and advance medical care for the future. All clinical trials are approved by an independent Institutional Review Board (IRB) to ensure a high level of safety and oversight. Interventional research trials determine whether new treatments or new ways of using known therapies are safe and effective.

At Chesapeake Urology Research Associates (CURA), one of the country’s largest practice-based urologic research programs, participants are closely monitored by our knowledgeable, experienced physicians, also known as investigators, as well as our highly-trained clinical research coordinators. Our experienced team is not only passionate about the positive impact of research on the development of new therapies, but also about the human aspect of research, which offers new hope for a brighter future to so many people. The CURA team is committed to providing compassionate care with expertise and integrity.

Research offered at Chesapeake Urology Research Associates may improve a patient’s quality of life in ways which would not have otherwise been possible.
Benefits of clinical trials

With over 60 active clinical trials, the CURA research team is focused on the development of new drugs, procedures, devices and surgical techniques to treat a wide variety of urologic disorders such as cancers of the prostate and bladder, urinary incontinence and kidney stones, to name a few.

Participating in a clinical trial has many potential benefits. These include:

• Access to the latest treatments before they are widely available.
• Closer monitoring of your condition by expert medical professionals.
• Improved medical knowledge that can benefit others.
• Being actively engaged in the management of your own healthcare.
• Enhanced care that not only can improve your quality of life but also can help to better the lives of other patients through the information that is gathered.
• Some participants may receive compensation for their time and reimbursement for extra services.

Extending hope to millions through research

The benefits that research has to offer to patients are far reaching. Clinical research enables investigators to gather important information that helps the public with a wider understanding of certain diseases and their treatments. Clinical research also offers:

• Greater access. Clinical trials provide access to cutting-edge treatments that are not yet available to the public. Some of the drugs that are part of the clinical trials cost thousands of dollars a month. Through the trials, some patients who can’t afford these treatments are given access at no charge, along with those who are not insured or who are under-insured.

• Life-changing treatments. These investigational treatments can be life-changing, especially to patients who have a very advanced cancer diagnosis and have exhausted all FDA-approved therapies.

• Hope. For patients who have failed other therapies for a particular disease, clinical trials provide access to potential new and effective treatments, not to mention hope for the future and an improved quality of life.

Clinical trials are investigational studies that are carefully designed to minimize risk and maximize benefits to all participants. Research studies are necessary in order to develop new treatments, and may be as short a one year, or for some cancer clinical trials, as long as five to seven years. In fact, the average length of time to develop a new drug or device, from patent to FDA approval, is upwards of 12 years at an average cost of $1 billion dollars!
Phases of clinical trials

Clinical trials usually involve several steps, or phases. Each phase answers a specific research question.

- **Phase I** - Phase I trials are the beginning of human testing of a new treatment. In this initial phase, a small number of participants are tested to assess the safety of a particular treatment or new drug.

- **Phase II** – Phase II trials test the ideal drug dosage with a larger group of participants to measure effectiveness of the treatment. This phase continues to assess safety.

- **Phase III** – Phase III trials are larger studies to assess the safety, efficacy and side effects of a new treatment. In this phase a drug, for example, is compared to commonly used therapies in order to collect information on effectiveness and safety.

- **Phase IV** – These studies are performed after the treatment has been put on the market to continue to collect data on the treatment’s effectiveness in different populations. Information on safety and side effects of the treatment also are gathered in this phase.

The majority of CURA trials are Phase II-IV. Therefore, our patients are usually not among the first group of people exposed to an investigational therapy, and there is already some data collected on its safety and efficacy.
Determining your eligibility

While participation in a clinical trial is voluntary, participants must meet strict inclusion and exclusion criteria. Determining eligibility is a process.

1. First, the CURA research team will review your medical record to make sure you meet basic eligibility criteria.

2. The staff will look for several variables depending on the study requirements (e.g., do you have an official diagnosis for the condition being studied? Is your PSA level high enough? Do you have enough metastatic lesions? Have you had a kidney stone in the past year? Are you currently taking any prohibited medications or therapies?).

3. Based on this medical record review, if you meet basic eligibility criteria, you will be contacted by your urologist and/or the study coordinator to initiate what is called the “informed consent process.” This involves reviewing a document that outlines the details of the research study (e.g., why the research is being done, what the procedures are, potential risks/benefits, etc.). You will review this information with the study staff. You may take as much time as you need to process the information, ask questions and discuss any concerns you may have.

4. After you consent to be considered for the trial, the staff will then conduct an in-person screening assessment. This involves various tests and/or procedures to ensure you meet all criteria to be enrolled into the study. The assessment typically includes: a thorough medical history including current medications you take on a regular basis, checking blood pressure, collecting specimens for lab testing (blood and/or urine), performing an EKG assessment, a physical exam, and other tests required by the study protocol. The results of these tests will officially determine whether or not you can participate in the clinical trial.

What to expect

While each clinical trial is different, you generally will work with a health care team that includes one of CURA’s physicians and a research coordinator. This team will follow a research protocol where all participants in an assigned group get the same tests and treatment.

Our team will check your health, carefully monitor you during the study, follow up with you after the study and focus on your overall comfort and safety. It’s important to take all prescribed treatments, keep all scheduled visits and inform the research team of any changes in your health or medications. You can also expect your research coordinator to provide you with new information and education about the study as it becomes available.

Remember: Enrolling in a trial is strictly voluntary and you may withdraw for any reason at any time.

Also, participating in a research trial will not affect your regular medical care.
About Chesapeake Urology Research Associates

Chesapeake Urology Research Associates (CURA) is a division of Chesapeake Urology Associates and is one of the largest urologic practice-based research programs in the country. The CURA team consists of experienced principal investigators, certified clinical research coordinators in several Chesapeake Urology locations who are dedicated to your personal care, a quality assurance/regulatory specialist as well as a research liaison and recruiter. Our investigators bring extensive experience and knowledge to all clinical trials and to your treatment. Patient safety is our primary concern and all members of the CURA team conduct research and follow Good Clinical Practices (GCPs) and International Council Harmonisation (ICH) Guidelines.

Medical Director

Ronald F. Tutrone, M.D., F.A.C.S., C.P.I., serves as CURA’s Medical Director and is also Chief of Urology at Greater Baltimore Medical Center (GBMC). Dr. Tutrone has been a principal investigator for more than 100 phase I, II and III clinical trials covering a broad range of urological conditions ranging from prostate, kidney and bladder cancers to urinary incontinence, kidney stones and prostate disorders.

Certified clinical research coordinators

Our certified clinical research coordinators (CCRCs) are experienced in all phases of clinical protocols and work closely with you throughout the clinical trial process. CCRCs provide guidance, information and education on the research protocol and work hard to ensure your safety and comfort throughout the study.

In addition, many of the physicians at Chesapeake Urology are involved in clinical research trials for a variety of urologic conditions. Talk to your urologist to find out more about clinical trials in which they may be involved.

Access to CURA’s extensive clinical trials program

With more than 60 active clinical trials, CURA offers an ever-growing range of research options for men and women living with urologic conditions including:

- Prostate cancer (The majority of CURA’s trials involve prostate cancer treatment, and studies are available for patients at all stages of the disease.)
- Bladder cancer
- Enlarged prostate/BPH
- Erectile dysfunction
- Interstitial cystitis (Painful bladder syndrome)
- Kidney stones
- Overactive bladder
- Pelvic prolapse
- Premature ejaculation
- Urinary incontinence

For information on current open clinical trials at CURA, please visit www.chesapeakeurology.com/specialties/clinical-trials or contact the research location nearest you.

“The research team’s primary focus is on the well-being and safety of our patients. We want to offer our patients the most advanced, cutting-edge care available, and our research program makes that possible.”

- Dr. Ronald Tutrone