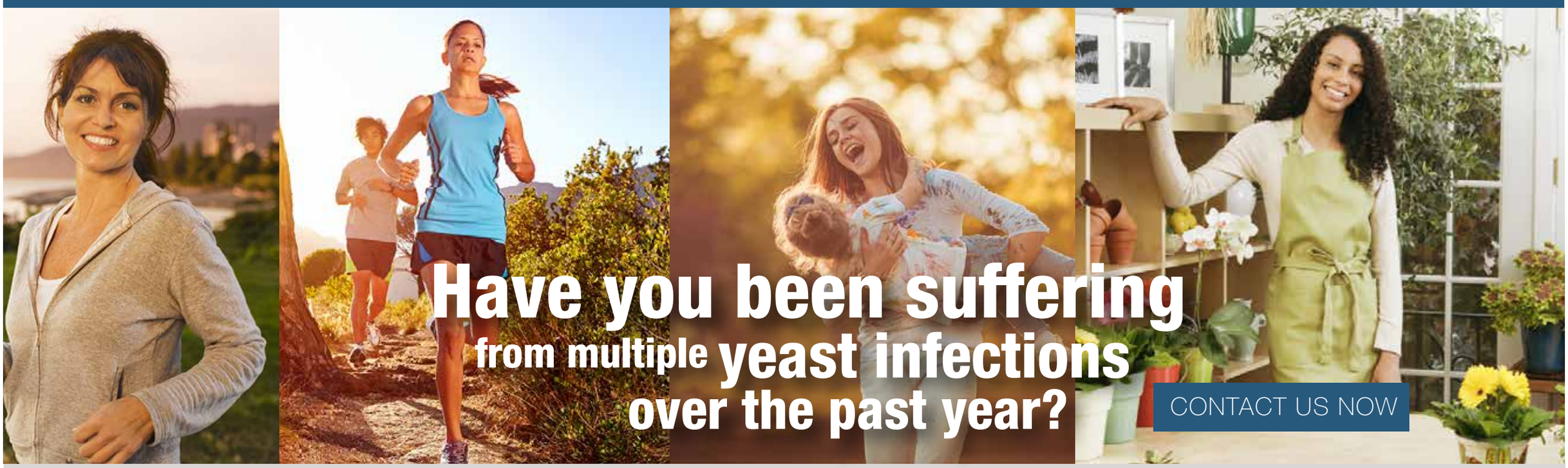
REVIVE

An Investigational Study for the Treatment and Prevention of Recurring Vaginal Yeast Infections

To speak with a study representative call

866-460-2836



REcurrent **V**ulvovaginal Candidiasis **I**nhibition; an Oral **V**T-1161 Tablet **E**valuation

Vaginal yeast infection, also known as vaginal thrush or vulvovaginal candidiasis, is a common fungal infection of the vagina. This infection occurs when there is an overgrowth of yeast in the vagina.

Up to 75% of women will experience this infection at some point in their lives, and approximately 5 - 8% will have recurring episodes. Common symptoms include: itching, burning, inflammation, abnormal vaginal discharge, discomfort and pain. Women who suffer recurring infections may have **R**ecurrent **V**ulvo**V**aginal **C**andidiasis also known as **RVVC**.

Occasional yeast infections can often be treated with antifungal medications, supplied as creams, tablets, or suppositories. However, there are no approved treatments for recurring yeast infections. Doctors are currently conducting a new research study for women suffering from RVCC.

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ABOUT THE STUDY

If you have been suffering from multiple yeast infections over the past year, you may want to learn more about this clinical research study. Doctors are currently conducting a clinical research study to evaluate the safety and effectiveness of an investigational oral tablet for recurrent vaginal yeast infections.

In order to qualify for this clinical research study:

- You must be between the ages of 18 and 64 years old
- You must be experiencing symptoms of a yeast infection, which include:
  - Vulvovaginal itching
  - Burning
  - Irritation
  - Vaginal discharge
- You must have experienced at least 3 yeast infections in the past 12 months (including the current infection)
- You must not be currently using over-the-counter or prescribed medication for your infection

Eligible study participants will receive study-related examinations, lab tests and study medication at no charge. Compensation for travel expenses may also be available.

FIND OUT IF YOU QUALIFY

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QUESTIONNAIRE

In order to participate in the study you must:

1. Be female
2. Be between the ages of 18 and 64
3. Currently have an active vaginal yeast infection
4. Have experienced at least 3 yeast infections in the past 12 months (including the current infection)
5. Not be pregnant
6. Not be lactating
7. Not have participated in a clinical trial in the past 30 days

If you meet these criteria and are interested in participation, please CLICK HERE to be contacted by a study representative.

ABOUT CLINICAL RESEARCH -FAQs

What is a clinical investigator?

A clinical investigator is a medical researcher conducting a clinical research study. Researchers are usually doctors, nurses, or other medical professionals.

Are clinical studies safe?

Clinical studies are typically conducted by a trained medical professional. An Institutional Review Board or IRB reviews all clinical studies. This is a committee made up of doctors, ethicists, health care administrators and members of the general public. This group helps to ensure that a study does not represent an unreasonable risk to individuals who are participating. Your regular doctor is responsible for your well-being and you may want to speak with your doctor before agreeing to participate in a study. Whenever you agree to enter a study, you are given the name and telephone number of a contact in your study physician's office who will answer your questions as well as a contact for the IRB whom you can contact if you have questions or concerns.

Why do people participate in a clinical study?

There are many reasons people take part in research studies. It gives individuals a chance to receive investigational medicine not available to the public. Studies are performed to test if the investigational study drug works and to see if it is safe.

Often, the process of collecting information in the study will allow you and the doctor to find out more about your disease and the effects it has on you. This may allow you to benefit from better treatment. Lastly, a study may not benefit you directly, but the information gathered may be of help to other individuals in the future with the same condition. Many study participants derive satisfaction knowing they may be a part of the effort to potentially reduce the suffering of other people in the future. Without participants, clinical trials to evaluate potential new treatments cannot happen. Clinical research trials help create the knowledge needed to find effective treatments for disorders such as RVVC.

How will I know if I am eligible for a clinical study?

You can find out about clinical studies from many sources. There are often advertisements in your doctor's office. Many clinical studies are posted on Internet pages such as this one and can be an excellent source of information. Each study has certain requirements for participation. Your study doctor will take a medical history from you and may request additional testing to determine if you are eligible according to the criteria for the study.

What is an informed consent?

Anyone agreeing to participate in a clinical study is required to sign an informed consent document. The informed consent document provides the details about the study and explains the potential risks and benefit. In addition, the informed consent document explains your rights and responsibilities. The informed consent document will tell you what study drug will be given, what kind of side effects might occur, and what other medications might work for your condition.

What is a PHASE in a clinical study?

Most clinical studies are carried out in steps called phases. Each phase is designed to find different information. Prior to entering the phases of human clinical studies, the study medication goes through extensive preclinical study testing on animals to justify clinical studies. Participants may be eligible for studies in different phases depending on their general condition, the type and stage of their condition, and what therapy, if any, they have already had. Participants are seen regularly to determine the effect of the study drug, and the study drug is typically stopped if side effects become too severe. (See the phase descriptions below.)

Phase I studies are primarily concerned with assessing the study drug's safety. This initial phase of testing in humans is done in a small number of healthy volunteers (20 to 100), who are usually paid for participating in the study. The study is designed to determine what happens to the study drug in the human body--how it is absorbed, metabolized, and excreted. A phase I study will investigate side effects that occur as dosage levels are increased. This initial phase of testing typically takes several months. About 70 percent of experimental drugs pass this initial phase of testing.

Once a drug has shown initial safety, it is then tested in a larger group of people to further evaluate the safety and effectiveness. This second phase of testing may last from several months to several years and involve up to several hundred participants. Most phase II studies are randomized, i.e. the treatment is allocated by chance or randomly. One group of participants will receive the experimental drug while a second "control" group will receive a standard treatment or placebo (an inactive look alike substance). Often these studies are "blinded"--neither the participants nor the researchers know who is getting the experimental drug. In this manner, the study can provide the pharmaceutical company information about the relative safety of the new study drug and its effectiveness.

In a phase III study, a study drug is typically tested in several hundred to several thousand participants. This large-scale testing provides the pharmaceutical company with a more thorough understanding of the study drug's safety, effectiveness, benefits, and the range of possible adverse reactions. Most phase III studies are randomized and blinded studies. Phase III studies typically last several years. Seventy to 90 percent of drugs that enter phase III studies successfully complete this phase of testing. Once a phase III study is successfully completed, a pharmaceutical company can request regulatory/government (for example, FDA) approval for marketing the study drug.

In late phase III/phase IV studies, pharmaceutical companies have several objectives: (1) studies often compare a study drug with other drugs already in the market; (2) studies are often designed to monitor a study drug's long-term safety, effectiveness and impact on a participant's quality of life; and (3) many studies are designed to determine the cost-effectiveness of a drug therapy relative to other traditional and new therapies.

For additional information on clinical trials, please visit www.clinicaltrials.gov

▶ STUDY LOCATIONS

PARTICIPATING DOCTOR'S OFFICES
Thank you for your interest in the RVVC clinical research study. Participating doctors' offices in this clinical study are in the following areas:

Alabama

University of Alabama Birmingham
Birmingham, Alabama, United States

Arizona

Women's Health Research
Phoenix, Arizona, United States

Arkansas

NEA Baptist Clinic
Jonesboro, Arkansas

California

Axis Clinical Trials
Los Angeles, California

Genesis Center for Clinical Research
San Diego, California

Florida

Altus Research
Lake Worth, Florida

Healthcare Clinical Data
Miami, Florida, United States

Vision Clinical Research
Palm Beach, Florida, United States

Clinical Research of West Florida
Tampa, Florida, United States

Physician Care Clinical Research LLC
Sarasota, Florida

Louisiana

Clinical Trials Management LLC
Covington, Louisiana, United States

Clinical Trials Management LLC
Metairie, Louisiana, United States

Kansas

Cypress Medical Research Center
Wichita, Kansas

Michigan

Wayne State University
Detroit, Michigan, United States

Beyer Research
Kalamazoo, Michigan

Nevada

Clinical Research of Nevada
Las Vegas, Nevada

New Jersey

OB/GYN Clinical Research
Lawrenceville, New Jersey

Women's Health Research Center
Plainsboro, New Jersey

New Mexico

New Mexico Gynecology Southwest Clinical Research
Albuquerque, New Mexico

New York

Suffolk OB-GYN
Port Jefferson, New York

North Carolina

Lyndhurst Gynecologic Assoc.
Winston Salem, North Carolina

Eastern Carolina Women's Center
New Bern, North Carolina

Unified Women's Clinical Research -Raleigh
Raleigh, North Carolina

Ohio

Radiant Research
Akron, Ohio

Pennsylvania

Drexel University College of Medicine
Philadelphia, Pennsylvania

Magee Women's Hospital
Pittsburg, Pennsylvania

Texas

Brownstone Clinical Trials
Fort Worth, Texas

Brownstone Clinical Trials
Irving, Texas

Clinical Trials of Texas
San Antonio, Texas

TMC Life Research, Inc.
Houston, Texas

Utah

Physician's Research Options LLC
Sandy, Utah

Virginia

Tidewater Physicians for Women
Norfolk, Virginia

Washington

Seattle Women's Health Research Gynecology
Seattle, Washington