STUDY BROCHURE

Information about a new clinical trial

Fighting yeast infections together

Recurrent yeast infections (also known as recurrent vulvovaginal candidiasis) can be both physically and emotionally uncomfortable to deal with. But current treatments don't work for everyone. So, we're looking for women and girls (12+) to join the VIOLET clinical trial and help us test a promising investigational drug.

To qualify, you must (among other things):

- Have had at least three yeast infections in the last year
- Have had at least one infection confirmed by laboratory/diagnostic test
- Be experiencing an active infection during your first visit to the study clinic
- Be otherwise generally healthy

This leaflet will tell you more about this trial specifically and about clinical trials in general. If you'd like to know more or have any questions, contact us for a confidential, no-obligation chat. We'll be happy to tell you more.

Clinical trials in brief

A clinical trial (also known as a clinical study) is a carefully controlled scientific investigation. The aim of each trial is to answer a specific set of questions. For example, one trial may ask if an investigational drug is safe and effective, while another may seek to learn if an existing medication for one disease can help people with another.

How are trial participants protected?

Every trial's plan (known as a 'protocol') must be approved by an independent committee before any patients can be enrolled. These committees ensure that the safety, rights and dignity of all participants are protected. Then, once a trial begins, the health of participants is monitored carefully during regular clinic visits.

Do I have to take part?

If you qualify to participate in this trial, the final decision as to whether you choose to take part is yours. No one can force you to join and your healthcare provider will not treat you any differently if you decide against it. Also, if you sign up but then change your mind, you're free to leave the trial even after you have started taking study medication. If you choose to leave, we would simply ask you to notify us and then return to the clinic for a final health check for your safety.

About the VIOLET trial

The investigational drug has already been tested in previous trials involving smaller groups of women with vaginal yeast infections. These smaller trials told us a lot about the investigational drug's safety and effectiveness (how well it works). For example, it was shown to work well in treating the yeast causing the infection, as well as being safe and tolerable. But now, we must carry out larger trials to confirm these findings.

What is the investigational drug?

Current therapies to treat yeast infections include creams applied directly to the affected area and oral drugs (known as 'azoles'). Fluconazole is one such azole, but it may only work for some people. What's more, azoles have been shown to sometimes cause unpleasant side effects and may not treat all infection-causing yeast.

So, the investigational drug has been designed to:

- Stop the growth of the yeast often responsible for the infection
- Have fewer side effects than other azoles
- Work after taking fewer doses than other azoles

What does participation involve?

At the initial visit, we'll explain the purpose of the VIOLET clinical trial, give you additional information explaining it in detail, and ask you to sign a consent form – signing the form shows that you agree to take part. Afterwards, you'll be screened to determine if you qualify. Eligible women and girls will then begin the following dosing schedule.

2 weeks

Eligible women/girls (i.e., those who pass screening AND have an active infection) will take 3 doses of fluconazole.

12 weeks

Infection gone after 2 weeks: Participants will take either the investigational drug or a placebo (which contains no medication) once a day for the first week, then once a week for the next 11 weeks.

Infection not gone after 2 weeks: Their participation will end.

36 weeks

We'll continue to monitor each participant's health.

Participants will be assigned randomly (by chance) to either the investigational drug or the placebo; neither participants nor the clinic team will know what each participant is taking. **Please note that all participants will be given fluconazole if an acute infection occurs at any time during the study.**

How will my health be monitored?

During the trial, participants will need to visit the clinic regularly so we can monitor their condition and general health. After your initial visit, these visits will take place on weeks 2 and 6, then every 6 weeks until week 48. On average, you'll be at the clinic between 45 minutes and 1 hour 15 minutes as we conduct assessments such as:

- **General health/ medication review**
- **Physical and vaginal examination**
- **Blood tests**
- **Complete questionnaires**
- **Infection signs/ symptoms review (plus vaginal fluid sample collected)**
- **Urine sample collected**
- **Weight measurement**
- **Pregnancy test**
- **Vital signs examination**
- **Heart examination**

If you'd like to know more about any of these assessments, please contact us. But please be reassured that no assessments will be carried out until we've explained the procedure to you in full and you're happy to continue.

Is there anything else that I should know?

Q **Are there any risks involved?**

A As with any medication, investigational drugs can cause some side effects. In addition, you may find that some trial assessments are uncomfortable (e.g., the vaginal examination or blood collection). However, please be reassured that your safety, comfort and dignity are our top priority.

Q **Are there any benefits to participation?**

A There may be several benefits to joining a trial. For example, regardless of its outcome, participants will contribute to our knowledge of yeast infections. Also, you may gain access to more frequent health monitoring or specialist attention than usual.

Q **Do I have to pay to participate in the trial?**

A Trial-related drugs and assessments will be provided at no cost. Health insurance is not required to participate.

Learn more

Thank you for your time and interest in this clinical trial. If you'd like to know more about the VIOLET clinical trial, contact us for a confidential, no-obligation chat. We'll be happy to answer any questions that you may have and to arrange a screening visit for you if you'd like to participate.

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