What are clinical research studies?

Clinical research studies help scientists and doctors explore whether a drug is safe and whether it works. Before a doctor can prescribe a new drug, it must go through several phases of clinical research:

1. **Phase 1:** First study of the drug in people (often healthy volunteers)
2. **Phase 2:** Study of the drug in people with the condition the drug is for
3. **Phase 3:** Study confirming how well the drug works
4. **Phase 4:** More research after the drug is approved

The pHlora study is a Phase 3 study.

Clinical research studies rely on volunteers. Remember that taking part in the study is your choice. Know that the rules and ethics that doctors must follow to practice medicine also apply to clinical research studies.

For more information about the pHlora study, contact:

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pH-D® FEMININE HEALTH

Do you experience recurring yeast infections?

Consider enrolling in the pHlora study researching a potential study medication for women with yeast infections.

Who can join the study?

You may qualify for the study if you meet the following requirements*:

- Nonpregnant, biological female, and 12 years of age or older
- Have symptoms of yeast infection

*Other criteria apply.

What is the purpose of the pHlora study?

The purpose of this study is to test the effectiveness of a study medication when used for women with vulvovaginal candidiasis (VVC), otherwise known as a yeast infection.

What is the study medication?

The study medication is a capsule inserted vaginally once a day. The medication contains boric acid, a natural chemical that may eliminate yeast overgrowth. Study participants will be randomly assigned to receive either the study medication or placebo. Placebo looks the same as the study medication but has no active ingredients.

Why should I join the study if I may receive placebo?

Whether you are assigned to receive the study medication or placebo, you make a positive impact on clinical research. The placebo group results help researchers identify if any health changes are from the study medication or another source. If you are in the placebo group, you have study visits, study assessments, and receive care from experts who specialize in your condition, just like the study medication group.

What can study participants expect?

Total participation for the pHlora study will last approximately 1 month. If you decide to participate, you can expect to complete the following steps:

Screening Period

- Receive assessments to determine if you qualify for the study. Assessments may include a urine test, pelvic exam, heart test, etc.

Study Medication Period

- Take your study medication once a day for 14 days.
- Complete a daily entry to your study eDiary with information about your study medication administration, any VVC symptoms, menstruation, etc.
- Visit the study clinic 1 time while taking the study medication for assessments.

Follow-up Period

- Attend 2 more visits to the study clinic after your last dose of the study medication for follow-up assessments.
- You will have a phone call with the study doctor between the 2 visits to the study clinic.