

ARE YEAST INFECTIONS

BOTHERING YOU OR A LOVED ONE?

A CLINICAL RESEARCH STUDY IS BEING CONDUCTED FOR WOMEN WITH A VAGINAL YEAST INFECTION.

YOU MAY QUALIFY FOR THIS STUDY IF YOU:

- Are currently experiencing symptoms of a vaginal yeast infection
- Are at least 12 years old

QUALIFIED PARTICIPANTS MAY RECEIVE:

- Compensation for time and travel
- All study medication and care at no cost

Version 1 Apr 10, 2019

QUORUM REVIEW
APPROVED
APR 12 2019
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Sponsor:	Scynexis					
Protocol:	SCY-078-303					
Indication:	Acute VVC					
Version & Date:	Ver 3 4/23/19					

Question Number	Inc/Exc Number	Question Text	Question Type	Answer Set	Qualifying Response	Supervisor Comments
0	OPTIN	Good Morning! / Good Afternoon! My name's [insert name here] and I'm contacting you on behalf of [site name and city/state]. Thanks so much for your interest in the yeast infection study. Is now [still] a good time to talk about this study? [if Yes, continue]. In case we become disconnected, can I confirm your call-back phone number is [patient phone]? To determine if you may qualify for this study, I'd like to ask you just a few questions about your medical history. This information will be kept confidential and won't be shared without your permission. Some of these questions may be sensitive in nature such as questions about HIV. Of course, you may end this phone call at any time, and please feel free to ask me any questions. Also, this call may be monitored or recorded for quality assurance and recordings are kept confidential to Studykik only. If you pre-qualify for this study, I will need to provide the information from this questionnaire to the research site in order for them to further discuss the study with you. We will try to connect you with the site staff at the end of this call, or if they're unavailable to take the call, they will contact you within the next 48 hours to set up an appointment. May I have your permission to continue?	Yes/No	Yes/No	Yes	
0	INFO	The purpose of this clinical research study is to evaluate the safety and effectiveness of an investigational drug in the treatment of vulvovaginal candidiasis, also known as a yeast infection, in women and girls. Study participation includes up to 4 clinic visits over a total duration of up to approximately 30 days. Qualified participants may be compensated for time and travel and compensation amounts may vary by research site. Do you think you might be interested in participating?	Yes/No	Yes/No	Yes	
1	GPS	Can I please have your zip code so I can make sure this site is in a convenient location for you? [Go to https://www.zip-codes.com/distance_calculator.asp and use patient and site zip code]	Yes/No	Yes/No	Yes	If patient says its too far, proceed and follow "Move Process" instructions for finding a better location
2		Before we proceed, if you are calling for your child, can you confirm you are the parent or legal guardian of the child that is interested in this study?	Yes/No	Yes/No	Yes	If No, stop and explain to the caller that the child cannot be considered for this study. Inform them that the child's information will be removed from the site's records.
3	INC1	May I please have your age and date of birth, or if calling for your child, their age and date of birth?	Age	Yes/No	12 and older [mark YES if 12 and older]	capture DOB in DB
4		If calling for a child, I should warn you that not all clinics offering this study will enroll minors. I will now check to see if the clinic nearest to you does accept minors.		Yes/No	Yes, clinic accepts ages 12 and older.	Agent to reference campaign number and see if on list of campaigns/sites that will not enroll minors. Exclude if site does not take minors. The following campaigns do not accept minors, [insert list here].
5	INC2	Have you, or the child you're calling for, been diagnosed with a yeast infection or believe you currently have a yeast infection? Symptoms may include a burning sensation, redness, swelling, pain, soreness, itching and irritation of the vagina and vulva.	Yes/No/Unsure	Yes/No/Unsure	Yes/Unsure	Do not DNQ if patient is unsure.
6	INC4	To participate in this study, women, and girls 12 and older, capable of becoming pregnant must use abstinence, or a form of birth control during the study, and for 10 days afterwards. The clinic staff will discuss acceptable forms of birth control with you. Are you, or the child you're calling for, willing to do this?	Yes/No	Yes/No	Yes	Women who are postmenopausal, had a hysterectomy, had both ovaries removed or those with a vasectomized male partner are not required to use birth control. Document in notes if these apply and continue.
7	INC4	Are you, or the child you're calling for, currently pregnant or breastfeeding?	Yes/No	Yes/No	No	
8	EXC8	Have you, or the child you're calling for, been diagnosed with HIV (Human Immunodeficiency Virus)?	Yes/No	Yes/No	No	
9	EXC5, EXC8	Do you, or the child you're calling for, have a history of cervical cancer, any forms of vaginal cancer, or are currently receiving chemotherapy?	Yes/No	Yes/No	No	
10	EXC2	Have you, or the child you're calling for, taken any antifungal pills, or used any topical antifungal creams, within the past 28 days?			DO NOT DNQ	Please notate the name and when the treatment was last taken.
11	EXC10	Have you, or the child you're calling for, participated in any investigational research studies within the past 30 days?			DO NOT DNQ	Please notate if the patient is currently in the study, or when they finished their participation.

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100	QUAL	<p>Based on your answers to the pre-screening questions, it looks like you may be eligible for this clinical trial!</p> <ul style="list-style-type: none"> • Enroll in Study: <p>Now, I'll transfer you to the research site so that you can speak to a member of the study staff who can schedule your first appointment. If the study coordinator isn't available, I'll contact them separately and ask them to call you within the next 48hrs. They may have a few additional questions for you. Is there anything else that I can help you with before transferring? I hope you have a great experience at [site name] Have a great rest of your day!</p> <ul style="list-style-type: none"> • If No Answer at Site: <p>I'm so sorry, but the study coordinator is currently with a patient. I'm going to transfer all the information that you've shared with me to the site and someone will be in touch with you within 48 hours. If they don't reach out, please call me back at (XXX-XXX-XXXX). Is there anything else I can help you with at this time? I hope you have a great experience at [site name] Have a great rest of your day!</p>				
101	DNQ	<p>I'd like to thank you so much for your time and for providing that information. Unfortunately, you don't qualify for this trial, but there may be studies in the future that could be of interest to you or your family. Would you like [site name] to retain your information and call you back about other study opportunities?</p> <ul style="list-style-type: none"> • If No → I understand. Explain to the patient that they won't be contacted for future studies without retaining this information. Inform the patient that their information will be removed from our records. Ask if there is there anything else you can help them with today. • If Yes → Perfect! Explain to the patient that the information obtained today will be provided to the site and that the site will contact them when there is another research opportunity. Ask if there is there anything else you can help them with today. 				