Promoting CSD500 Use among Women in Established Relationships
NCT02934620
Enrollment Consent Form

The Enrollment Consent Form was last revised on December 28, 2016. The IRB approved the revision on January 31, 2017.

VN CSD500 Study
Enrollment Condom Form

Introduction

The Ministry of Health in Vietnam and The Ohio State University in the U.S. are conducting a research study to learn more about the acceptability and use of a new condom called Futura Max.

I would like to tell you about this study so that you can decide if you want to take part. You can choose to join or not to join this study. Please ask questions at any time if anything is unclear.

Purpose of the study

This study will learn about the acceptability and use of a new condom, Futura Max. Futura Max has a small amount of gel inside of it that can increase the local flow of blood in the penis. This can make the man wearing the condom have a harder and longer erection. The new condom is approved to be sold in countries in Europe but not in Vietnam.

Study overview

There will be about 500 couples in the study. We will put couples in the study into two groups by chance, which works like flipping a coin. One group will get Futura Max condoms and the other group will get standard condoms. Both groups are important to help us learn about condom acceptability and use. We do not know which condom you will get before you join the study.

The study has four visits for women: the visit today and visits in 2, 4 and 6 months. The study has two visits for men: the visit today and a visit in 6 months. All visits will last about 60-90 minutes.

Procedures

Now I want to tell you what will happen today if you are both eligible and if you both decide to join the study.

- We will ask you both questions about your personal history, medical history and condom experience. The questions will take about 30 minutes for each of you to answer.
- We will talk to you about using condoms and give you the study condoms to take home to use.
- The doctor will collect a vaginal swab from the woman to test for semen in her vaginal fluid. We will send the swabs to the University of North Carolina in the U.S. for this testing. This test result will not be used to help with your medical care.
- We will give the woman an appointment to come back in two months.
- If you do not return for the other study visits, a study staff person will contact you. We will ask later today how you would like to be contacted, and we will respect your privacy as to how you would like to be contacted.

Now I want to tell you what will happen at the woman's next three study visits.

- We will ask the woman to return in 2, 4 and 6 months.
- At these visits, we will ask you more questions about your sexual behaviors and experiences with the condoms since your last study visit. These questions will take about 30 minutes.
- We will give you more of the study condoms to take home to use.

- At these visits, the doctor will collect another vaginal swab to test for semen in vaginal fluid. We will send the swabs to the University of North Carolina in the U.S. for this testing. These results will not be used to help with your medical care.

Now I want to tell you what will happen at the man's next study visit in six months.

- We will ask you more questions about your sexual behaviors and experiences with the condoms since your last study visit. These questions will take about 30 minutes.

Risks

Now, I will talk to you about the possible problems you could have if you decide to take part in this study. You might feel embarrassed or anxious when you are answering questions about your sexual behavior. You may choose not to answer any question for any reason. If you tell us that you don't want to answer a question, we will just move on to the next one.

Some people have reported headaches, faintness and nausea, loss of sensation, dizziness or skin irritation when using CSD500 condom.

Potential benefits

There are no benefits to you to being in this study. Others may indirectly benefit in the future from the trial results.

Privacy

Now I want to talk to you about privacy. Any information that you give us during the study will be kept private. To protect your personal information, we will use a code number for your study records instead of your name. We will keep the records locked up and only let study staff and people paying for the study look at them. Your name or other facts that might point to you will not appear when we present this study or publish its results.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, and vaginal samples. The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact ***Dr. Nghia Nguyen at 01229355689***, if you have questions.

You may also visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

Costs and compensation

There is no cost to you for being in this study. We will compensate you at the end of each study visit for your time and transportation costs. Women will receive 110,000 VND at the end of the visit today; 110,000 at the visit in 2 months; 220,000 VND at the visit in 4 months; and 440,000 VND at the visit in 6 months. Men will receive 110,000 VND at the end of the visit today and 330,000 VND at the visit in 6 months.

Your rights to refuse or withdraw

Now, I would like to finish by talking about your rights as a person who takes part in the study.

You can choose to join this study or not. Also, if you join the study, you can also choose to drop out of the study later for any reason. If you do not join the study or if you drop out of the study, this will not affect your routine health care that you receive here. Study staff could remove you from this study without your permission if they decide that it is best for your health or for the study. Also, the people doing this study may stop this study at any time.

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. You may choose to be referred for other contraception instead of joining this study.

Participant statement and signature

Did you understand everything I have talked about? Do you have any questions?

If you agree to take part in the study, I will read you a statement and ask for your signature of consent.

- *This study has been explained to me.*
- *The questions I asked today have been answered.*
- *I agree to take part in this study.*

*If I have questions or comments about the study, I can go see the study doctor at this clinic. I can also call **Dr. Nghia Nguyen at 01229355689** if I have questions or if I feel that I have been harmed by being in this study.*

*Ethical review committees at the Hanoi University of Public Health and at the Ohio State University in the U.S. have reviewed and approved this study to make sure that the rights of research participants are protected. If I have questions about my rights as a research volunteer, I can contact **Ha Van Nhu, MD, PhD at the Hanoi University of Public Health at 04-6266-2347.***

I received a copy of this form.

Please check one box:

☐ I [female and male volunteer] give consent for study staff to contact me in the future to tell me about any new studies.

☐ I [female and/or male volunteer] **DO NOT** give consent for study staff to contact me in the future to tell me about any new studies.

Signature or Mark of Female Volunteer **Date**

Printed name of Female Volunteer

Signature or Mark of Male Volunteer **Date**

Printed name of Male Volunteer

Witness' signature (needed if the volunteer is unable to sign)

I was present throughout the entire consent process with the volunteer. All questions from the volunteer were answered and the volunteer has agreed to take part in the research.

Signature of Witness **Date**

Printed Name of Witness

Investigator's (or designee's) signature

I have read this form to the volunteer and have answered all of the volunteer's questions.

Signature of the Investigator (or Designee) **Date**

Printed Name of the Investigator (or Designee)