The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title:
A randomized trial comparing perioperative pelvic floor physical therapy to current standard of care in transgender women undergoing vaginoplasty for gender affirmation

Principal Investigator:
Cecile A. Ferrando, MD MPH 216-444-0642
After hours phone contact: 216-444-2200, ask for the Gynecologist on call

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you are scheduled to undergo gender confirmation surgery. The purpose of this study is to compare the effectiveness of pelvic floor physical therapy (PFPT) before and/or after your surgery (this is normally referred to as the perioperative period). Currently, PFPT is not standard of care for all patients who undergo gender confirmation surgery. While some practices have implemented these new programs, and data exist on outcomes associated with PFPT in transgender women undergoing gender confirmation surgery, no study has compared the implementation of perioperative PFPT to routine care (no perioperative PFPT).

You will need to attend up to 3 pelvic floor physical therapy sessions before and/or after your surgery. You will fill out questionnaires during your normally scheduled pre and postoperative visits. In addition to attending between 1 to 3 physical therapy sessions before and/or after your surgery, you will need to complete questionnaires during your scheduled pre and postoperative visits.

Your participation in the research will last approximately 12-weeks after your surgery.

More detailed information can be found under the section labeled: “Information on the Research.”

Why might you choose not to participate in this research study?

You may choose not to participate in this research study and still undergo the surgery by your doctor.

More detailed information about the risks of this study can be found in the section labeled "Risks."

Why might you choose to volunteer for this study?

You may not receive direct benefit from being in this study. However, taking part may help patients undergoing vaginoplasty in the future.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?

The alternative is not to participate and to undergo the surgery by your doctor. Physical therapy is still available after surgery if it is clinically indicated even if you are not in the study

More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

DETAILED INFORMATION

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

You are being asked to participate in a study because you are scheduled to undergo vaginoplasty (penile inversion) surgery with Dr. Ferrando. The study is looking at the effectiveness of pelvic floor physical therapy before and/or after vaginoplasty surgery. We currently do not know if adding physical therapy before and/or after surgery helps patients with their recovery and improves the outcomes of surgery.

How Many People Will Take Part In The Study?

Our goal is to enroll 40 patients undergoing vaginoplasty surgery with Dr. Ferrando. All women scheduled to undergo this surgery who meet our inclusion criteria will be asked to participate in the study.

What is involved if you decide to take part in this research study?

The research involves undergoing your scheduled vaginoplasty surgery. Participating in the study will not change any aspect of your surgery. Currently, PFPT is not standard of care for all patients who undergo gender confirmation surgery, and we will be randomizing you (like the flip of a coin) to one of three regimens before and/or after your surgery.

Once enrolled, you will be randomized into one of two groups:

- Postoperative PFPT
- No Postoperative PFPT

If you are randomized into the Postoperative PFPT group, you will be further randomized into one of the following sub-groups:

- Postoperative PFPT alone
- Preoperative and Postoperative PFPT

This means that you may have to attend up to 3 pelvic floor physical therapy sessions before and/or after the time of your surgery. Depending on the group you are assigned, you may only have to attend one session after your surgery. If the therapist you are working with decides that you need to attend more therapy to improve your surgical outcome that will be up to you and your therapist, and will not be part of the study protocol.

You will also be seen in the office one week after your surgery for dilation teaching and an exam. This office visit is part of your normal postoperative care.

In addition to attending 1 to 3 physical therapy sessions before and/or after your surgery, you will need to complete questionnaires during your normally scheduled pre and postoperative visits. Completion of the questionnaires will add approximately 10-15 minutes of additional time to your visits.

How Long Will You Be In The Study?
Your participation in this study will last approximately 12 weeks after your scheduled surgery.

2. ALTERNATIVES
What are the alternatives to participation in the research study?
Taking part in this study is voluntary. The alternative to participating is not to participate and to undergo the surgery by your doctor. Your decision not to participate or to withdraw from the study will not impact your planned surgery. Physical therapy is still available after surgery if it is clinically indicated even if you are not in the study

3. RISKS
What are the risks of participating in the research study?
You will receive a variation of the same treatment you would receive if you were not participating in the study. We currently use physical therapy to manage our patients after vaginoplasty surgery. The risks of physical therapy are minimal; however, you may experience pain and soreness after therapy. If you are assigned to the control group and don't receive physical therapy after your surgery your outcomes might be worse.

Confidentiality Risks

There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the use of the following safeguards:

If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study. After that time it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

Questionnaire/Survey Research

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

4. BENEFITS

What are possible benefits of participating in the research?

You may not receive direct benefit from being in this study. However, taking part may help others undergoing vaginoplasty in the future.

5. COSTS

Are there any costs to you if you participate in this study?

There is no additional cost to you to be in this research study. All postoperative visits (both within and outside of the study) are included in the cost of your surgical procedure. **You are responsible for paying any deductibles, copayments or co-insurance** that are a normal part of your health insurance plan.

6. COMPENSATION

Are there any payments to you if you participate in this study?

You will receive a $25 gift card for participation in this study.

The IRS requires CCF to report payments to an individual of $600 or greater (in a calendar year) on a Form 1099-MISC. Your name, address and social security number will be collected to track the payments made to you and, if you receive $600 or greater, will be used to process a Form 1099-MISC.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

In the event you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

Authorization to Use/Disclose Protected Health Information

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research (Caldera Medical Inc.) and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing**, Cecile Ferrando, M.D., 9500 Euclid Avenue/A81, Cleveland, Ohio 44195.** If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Cecile Ferrando, M.D at 216-444-0642. After business hours, you may contact the Gynecologist on call by calling the Cleveland Clinic page operator 214-444-2200. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. SIGNATURES

Statement of Participant
I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this study and any research from the data in the study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion
I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date

If needed for remote consenting:

_____
Printed name of Witness (Remote Consenting)

_____ _____
Signature of Witness (Remote Consenting) Date