IRB APPROVED
Dec 28, 2020

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

TITLE: Comparison of Collagenase Clostridium Histolyticum to Surgery for the Management of Peyronie's Disease: A Randomized Trial

PROTOCOL NO.: CUREPD101
IRB Protocol #20203547

SPONSOR: Endo Pharmaceuticals

PRINCIPAL INVESTIGATOR:
Landon Trost, MD
1443 W 800 N Ste 202
Orem, Utah 84057
United States

STUDY-RELATED PHONE NUMBER(S):
888-655-0015
507-202-1995

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at the Male Fertility and Peyronie's Clinic now or in the future if you choose not to participate or discontinue your participation.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator(s): Landon Trost **Study Team Contact:** Holli Burgon	**Phone:** 801-655-0015 507-202-1995 **Phone:** 801-655-0015 **Institution Name and Address:** Male Fertility and Peyronie's Clinic 1443 W 800 N, Suite 202 Orem, UT 84057	▪ Study tests and procedures ▪ Research-related injuries or emergencies ***Any questions about the research or research related concerns or complaints*** ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Research Billing	(801) 655-0015	▪ Billing or insurance related to this research study

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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1. Why are you being asked to take part in this research study?

You are being asked to participate in this study because you have Peyronie's Disease and are a candidate for treatment with either collagenase Clostridium histolyticum (CCH - Xiaflex) or surgery.

2. Why is this research study being done?

The goal of the current study is to determine if patients are more satisfied with CCH or surgery. Additionally, we are seeking to learn how the two therapies compare in terms of short and long-term side effects and how satisfaction changes over time. The combination of penile traction therapy (PTT) with either surgery or CCH is considered investigational.

3. Information you should know

Who is Funding the Study?

Endo Pharmaceuticals (company that makes collagenase Clostridium histolyticum).

4. How long will you be in this research study?

You will be in this study for up to 60 months following the final treatment. During this time, we would anticipate that you would make two additional visits to the Male Fertility and Peyronie's Clinic.

5. What will happen to you while you are in this research study?

The current study is a randomized, clinical trial. If you are eligible for the study, we will assign you by chance (like a coin toss) to the collagenase Clostridium histolyticum and penile traction treatment or penile surgery and penile traction therapy group. Collagenase Clostridium histolyticum has been approved by the FDA for this purpose. You or your physician cannot choose your study group. You will have a 1 in 2 chance of being assigned to either group.

Following your consent, we will ask you to fill out questionnaires about your sexual health and will obtain a penile ultrasound and basic penile measurements. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires will take about 20 minutes to complete.

If you are assigned to the collagenase Clostridium histolyticum and penile traction group, you will undergo a total of 8 injections spaced out over approximately 18 weeks. Each injection will administer 0.58 mg of collagenase Clostridium histolyticum (standard dose). Additionally, you will be asked to use a penile traction device daily for 30-60 minutes until 3 months after your last treatment.

If you are assigned to the surgery and penile traction group, you will undergo a penile surgery. The penile surgery performed will depend on your specific condition. Men with curvatures less than 70 degrees will undergo a penile plication, while those greater than 70 degrees may undergo an incision and grafting procedure or penile plication. Incision and grafting will be performed in those who are less than60 years old and have normal erectile function without need for phosphodiesterase-5 inhibitors (Viagra, Levitra, Cialis, Stendra). Penile plication involves the placement of stitches on the opposite side of the curvature to result in straightening of the penis. Incision and grafting involves cutting into the point of maximal curvature and placement of a graft in the resulting gap.

About 2-4 weeks after surgery, you will be recommended to also utilize a penile traction device 30-60 minutes daily until 3 months after surgery.

In both groups, you will be asked to keep a daily diary of traction device use.

You will also be asked to return for office visits at 3, 12, and 60 months after completion of treatment. We will also ask you to complete questionnaires online at 6, 24, 36, and 48 months.

6. What are the possible risks or discomforts from being in this research study?

Nearly all procedures and interventions are considered standard of care. There are a few questions in the questionnaires that are specifically research-only in nature, and as such, there is the risk of accidental disclosure or breach of confidentiality. Additionally, there are inherent risks of randomization, whereby a physician has not specifically indicated a recommended treatment course. However, given that both options are considered standard of care, this latter risk is likely minimal. Similarly, current procedures are in place to minimize the likelihood for accidental disclosure / breach of privacy/confidentiality (password protected medical record and patient files, codified data such that patient demographic identifiers are not included in responses).

Common risks of collagenase Clostridium histolyticum include bruising of the penis, while less common side effects can include penile fracture. A penile fracture would not require further treatment. Risks of penile plication and incision and grafting include perceived or actual loss of penile length, changes in sensation (temporary or permanent), changes in erectile function, and bruising.

You will be fitted and instructed on how to use the penile traction device. Risks may include pain in your scrotum, penis or abdomen, skin discoloration, bruising or blistering, worsening of sexual function.

There also may be unknown risks from participation in the research study.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop.

In addition, the Principal Investigator or the Male Fertility and Peyronie's Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used. We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form, who will provide treatment or refer you to appropriate treatment.

Who will pay for the treatment of research related injuries:
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be billed for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. Some insurance companies will not pay for injuries sustained in research. You are recommended to contact your insurance company prior to enrolling if you have any concerns in this regard.

9. What are the possible benefits from being in this research study?

There are several potential benefits in being in the current research study. Benefits cannot be guaranteed. You may experience improvements in penile length and curvature. Other men with Peyronie's Disease may also benefit in the future from what we learn in this research study.

10. What alternative do you have if you choose not to participate in this research study?

You do not have to be in this study to receive treatment for your condition. You may seek treatment separately for Peyronie's Disease with injectable therapies, traction, or surgery. Talk to the Principal Investigator if you have any questions about any of these treatments or procedures.

11. What tests or procedures will you need to pay for if you take part in this research study?

You will not need to pay for any visits, tests, or procedures that are done just for this research study. These tests and procedures include:

- Penile ultrasound
- Penile length and curvature assessment
- Collagenase Clostridium histolyticum OR surgery (depending on which group you are assigned to)
- Penile traction device (RestoreX)

However, you and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of your medical care.

12. Will you be paid for taking part in this research study?

Any costs that you incur relating to travel (up to $500 per trip) will be reimbursed. You will also be given $600 for participating in the study (divided over 4 visits - $150 after initially completing treatment, $150 after completing the 3-month visit, $150 after the 1 year visit, and $150 after the 5-year visit). The maximum amount that you may receive will therefore depends on whether or not you incur travel-related expenditures to receive treatment and for follow-up visits.

13. How many people are expected to enroll in this study?

Up to 50 participants are anticipated to enroll in the study.

14. How will your privacy and the confidentiality of your records be protected?

The Male Fertility and Peyronie's Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Upon entry into the study, you will be assigned a subject ID, which will be used to record all data. All electronic

information will be kept on a Male Fertility and Peyronie's Clinic server and will be protected in a similar manner to your existing medical records. If the results of the research are made public, information that identifies you will not be used.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

The data obtained in this study will only be used for the present study and will not be shared for future research.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Male Fertility and Peyronie's Clinic research staff involved in this study.

With whom may your health information be shared?

- Other Male Fertility and Peyronie's Clinic providers involved in your clinical care.
- The Food and Drug Administration
- The Institutional Review Board overseeing this study

How long will my permission last?

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

May I review or copy my information?

Yes, but only after the research is over.

Is your health information protected after it has been shared with others?

The Male Fertility and Peyronie's Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside The Male Fertility and Peyronie's Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule. There is a risk that your information will be given to others without your permission.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with the Male Fertility and Peyronie's Clinic.

You will receive your own signed and dated copy of this document.

You can cancel your permission to use or share your health information at any time by sending a letter or email to the address below:

Male Fertility and Peyronie's Clinic
1443 W 800 N, Suite 202
Orem, UT 84057
email@mfp.clinic

Be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your consent and authorization to be in this study.

	/ /	AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	AM/PM
Printed Name	Date	Time

Signature