

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

Center for Vulvovaginal Disorders

SUBJECT INFORMATION AND INFORMED CONSENT FORM

Title of the study: **A double blind placebo-controlled trial of StrataMGT™ for the management of vulvar lichen sclerosus symptoms**

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Sub Investigators Leia Mitchell, PA-C,
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Protocol Number: CVVDOO5

Sponsor: Stratpharma AG

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KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a subject in a research study because you have lichen sclerosus.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	This is a research study to evaluate the effectiveness of StrataMGT, a silicone-based product to reduce the symptoms associated with lichen sclerosus.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	Your participation is expected to last 14 weeks
Procedures	The main procedures in the study: <ul style="list-style-type: none">• Vaginal cultures at the beginning of the study• Photographs of your genitals will be taken at the beginning and end of the study• Application of StrataMGT or placebo gel to the genital area
Risks	Taking part in this research may expose you to risks (side effects) of the study experimental product. Side effects may range from being mild to life-threatening and may go away with treatment or be permanent.

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	<p>The main risks for StrataMGT, the experimental product, is irritation of the skin or tissue to which it is applied.</p> <p>The study doctor will explain the risks of this research to you before you decide about participation.</p> <p>Not all risks of the study investigational product are known at this time.</p>
Benefit	<p>There is no guarantee that you will receive direct benefit as a result of your participation in this study. Possible benefits of study investigational product include decreasing symptoms associated with lichen sclerosis. The study results may help people in the future.</p>
Alternatives to Study Participation	<p>There are other topical products that may be applied to limit the symptoms associated with lichen sclerosis.</p>
Costs	<p>The study sponsor will provide the study experimental product at no charge to you and pay for the procedures that are required only for the study.</p>
Confidentiality	<p>There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information.</p>

This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

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INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends, and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

Stratpharma AG, the sponsor of this study, is providing funds to the Center for Vulvovaginal Disorders on a per subject basis for conducting this research study.

PURPOSE OF THE STUDY

You have been asked to participate in this research study because you have been diagnosed with lichen sclerosis.

Lichen sclerosis is a skin condition of the external genitals (vulva) of women. It causes vulvar itching, pain, and burning. In addition, lichen sclerosis causes scarring of the vulva which may cause significant sexual dysfunction or pain. Lastly, 4-6% of women with lichen sclerosis will develop vulvar cancer.

The current “gold standard” treatment for lichen sclerosis is steroid creams. When used correctly, steroid creams help to decrease the symptoms of itching and burning and can prevent further vulvar scarring. In addition, proper treatment reverses the underlying inflammation of lichen sclerosis, and may lower the risk of getting cancer. While useful, steroid creams may not completely relieve the symptoms associated with lichen sclerosis.

The experimental product is a proprietary formulated silicone-based gel called StrataMGT, which may reduce the severity of symptoms associated with lichen sclerosis. StrataMGT lightly bonds to form a protective layer that is waterproof but lets in gas, and hydrates and protects tissue.

The aim of the study is to test the effectiveness of StrataMGT, the experimental product, for the improvement in symptoms associated with lichen sclerosis as measured by three questionnaires that you will take four times during the study. Additionally, the investigator will assess the amount of inflammation associated with your lichen sclerosis by taking photographs of your genitals before and after the Strata MGT is applied.

Fifty percent (one half) of the participants in this study will get the study product and fifty percent (one half) will get the placebo (inactive gel). The determination is made at random, so everybody has a 50-50 chance of getting either one. Neither you, nor the study investigator will know if you received the study product or the placebo until the end of the complete study. Therefore you will not get this information when your participation in the study has finished.

NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION

Up to 100 subjects are expected to participate in this study at 2 research sites in the United

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States.

Your participation in this study is expected to last 14 weeks.

STUDY PROCEDURES

Visit 1 - Screening

- You will be asked detailed questions about your medical history
- You will fill out questionnaires about your itching, burning, soreness, and pain with intercourse.
- A physical examination will be performed including an examination of your vulva (genitals).
- A digital photograph of your vulva (genitals) will be taken.
- A swab will be inserted into your vagina for a vaginal culture.

Visit 2 – Week 2

- You will return approximately 2 weeks after visit 1.
- If you meet the inclusion criteria, you will have another examination of your genitals
- You will be given either the experimental product or the placebo gel and be instructed on its use.

Visit 3 – Week 8

- You will return approximately 6 weeks after visit 2.
- You will tell the study doctor if you are had any side effects from the experimental product/ placebo gel.
- You will bring the container of the experimental product/placebo gel with you to your visit so that it can be weighed.
- You will fill out questionnaires about your itching, burning, soreness, and pain with intercourse.
- A physical examination will be performed including an examination of your vulva (genitals).

Visit 4 – Week 14

- You will return approximately 6 weeks after visit 3.
- You will tell the study doctor if you are had any side effects from the experimental product/placebo gel.
- You will bring the container of the experimental product/placebo gel with you to your visit so that it can be weighed.
- You will fill out questionnaires about your itching, burning, soreness, and pain with intercourse.
- A physical examination will be performed including an examination of your vulva (genitals).
- A digital photograph of your vulva (genitals) will be taken.

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SUBJECT RESPONSIBILITIES

As a subject in this study, you will have certain responsibilities, including the following:

- Attend all study visits and, if needed, reschedule appointments as soon as possible
- Follow the instructions of the study staff
- Use the investigational product as directed
- You must bring in your container of the experimental product/placebo gel with you to each of your study visits so that it can be weighed.
- You must remain on your stable regimen (schedule of use) of topical steroids or topical calcineurin inhibitor for the entire study. If you were using vaginal estrogen at the beginning of the study you must remain on the vaginal estrogen but you may not use it on your vulva.
- Tell the study doctor all medications that you are taking and check with the study doctor before taking any new medicines or changing medications (including prescription, over-the-counter, vitamins and herbal supplements)
- Tell the study staff any time you do not feel well or if you have any side effects or have hospital or doctor visits

RISKS AND DISCOMFORTS

Allergic or irritant reactions

Staining of clothing or sheets (dry cleaning should be able to remove these stains without damage to fabric)

NEW INFORMATION

You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

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.

Clinically Relevant Research Results

As the results obtained during the research study are for research purposes only and are not for medical diagnosis, you will not receive individual results. In some circumstances, if the study doctor learns information related to your health from the study procedures, the study doctor will discuss this information and your options with you.

BENEFITS

We cannot promise any benefit to you or others from your participation in this research. However, possible benefits include improvement in symptoms related to your lichen sclerosis. The study results may help people in the future

ALTERNATIVES TO STUDY PARTICIPATION

You do not have to participate in this study to receive treatment for your condition. Alternative

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topical products may be used to treat the symptoms associated with lichen sclerosus. You may choose to have no treatment.

COSTS OF PARTICIPATION

The sponsor of this study will provide the study product at no charge to you. The sponsor covers the cost of assessments and procedures required only for this study.

You and/or your insurance company will be responsible for the costs of all items and services during the research study, which you would have received for your condition if you were not enrolled in this research study and/or that your physician believes are medically necessary to treat you. You should discuss possible costs of study participation with the study staff and/or your insurance company.

REIMBURSEMENT

You will receive \$100 for each completed in-clinic visit toward your study related expenses such as travel and parking. If you leave the study early, you will be reimbursed only for visits you complete. You will be reimbursed by check after your last study visit.

You will not receive payment of any kind for your information and specimens (even if identifiers are removed) or for any tests, treatments, products or other things of value that may result from this research study.

Tax law may require the payer (e.g. research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you received \$600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you received from the study.

COMPENSATION FOR INJURY

For medical emergencies, call 911. If you become ill or are hurt while you are in this study, contact your study doctor immediately. The study doctor will assist you in obtaining appropriate medical treatment. The Center for Vulvovaginal Disorders will not be responsible for the costs of treatment caused by the properly performed study procedures or the investigational product.

The sponsor will pay for reasonable and necessary medical treatment of injuries and illness that are a direct result of study investigational product and/or study procedures that are required by the study protocol and that were done correctly and only because you were in this study.

The sponsor will not cover the costs of your study-related injury or illness if:

- The sponsor and/or the study doctor do not think the condition or injury is a direct result of your being in the study;
- The injury is attributable to the underlying disease or a pre-existing medical condition or the natural progression of an underlying disease;
- The injury was the result of a failure to follow the study protocol or instructions or misconduct by the study staff.

No other compensation will be offered by the sponsor or the Center for Vulvovaginal Disorders

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or Biomedical Research Alliance of New York, including for things such as lost wages or discomfort. You are not waiving any legal right to seek additional compensation through the courts by signing this form.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA, and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study doctor's office for a final study visit for your safety.

CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

If you take part in this study, you will be assigned a unique subject code to help protect your privacy. Your study records and study samples will be labeled with this code that does not directly identify you. The study site staff securely stores the linking code between your name and study information.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays,

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- physical examinations, and medical history
- Billing records

Your race and/or ethnicity may be collected as part of this study. This information is used by the sponsor to find out if study results vary among different populations and to help determine if the study product may have different affects in certain populations.

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, contract research organization and study sites (if you transfer to another study site)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research

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study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review, correct, and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Your information and biospecimens collected as part of this research study, even if identifiers are removed, will not be used or distributed for future research studies.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies that are responsible for protecting your rights.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Andrew T. Goldstein at 202-887-0568 during normal business hours or at 410-279-0209 (24-hour number).

If you seek emergency care or hospitalization, tell the treating health care providers that you are in this research study.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research. The IRB is a committee that reviews research studies to help protect the rights and welfare of study subjects.

