Does topical steroids plus Mona Lisa Laser improve symptoms of Lichen Sclerosus compared to treatment with topical steroids alone?

Principal Investigator: Charles Hanes, MD

Co Investigators: Stephen Varner, MD, Hayden Kassels, MD, Catera Duhon, RN, BSN

Research Site: University of South Alabama Strada Patient Care Clinic

Institution: University of South Alabama Obstetrics and Gynecology Department

Funding Sponsor: No funding available

Version 1: October 8, 2021

Introduction

Vulvar Lichen sclerosus is a common benign dermatosis which causes pain and itching. Topical Steroids have been the main treatment modality. A recent study showed that fractionated CO2 laser treatment is non inferior and actually showed statistically significant improvement in subjective symptoms compared to clobetasol propionate steroid cream with no serious safety or adverse events. With steroids having a protective cancer benefit on lichen sclerosus, we hypothesize that steroids in additional to mona lisa laser will provide greater symptom relief while still providing the benefits of steroids on lichen sclerosus. This study will be following the clinical research protocol created and Good Clinical Practice standards and associated federal regulations.

Study Objectives

To assess the efficacy of laser with use of topical steroid versus topical steroid treatment alone for lichen sclerosus symptoms

Study Design

Primary Outcome: The primary outcome will be change in mean Skindex 29 score at 6 months.

Secondary Outcomes: Quality of life measurements using a subjective visual analog scale for bothersome vulvar symptoms, vulvovaginal symptoms questionnaire, and a global impression of improvement and satisfaction at six months. Secondary objective measures include provider assessment of vulvar appearance using an objective visual analog scale.

Subject Selection and Withdrawal

Inclusion Criteria: women with biopsy proven lichen sclerosus and significant symptoms based on Skindex-29 scores >21

Exclusion Criteria: prior vaginal mesh or pelvic radiation, or active genital infection

Subject Recruitment and Screening: The patients will be recruited by word of mouth in our OB/GYN clinic. Inclusion criteria includes biopsy proven lichen sclerosus.

Early Withdrawal of Subjects

Subjects that have any adverse effects, including worsening lichen sclerosus, severe irritation or any other safety reasons may withdraw from the study. Also subjects that do not adhere to the protocol may also be withdrawn. The subjects will also have to option to withdraw if they request.

Study Procedures

Risks: Risks to the subjects are minimal. The laser has been previously used for lichen sclerosus treatment and has been overall tolerated well. Potential side effects include vaginal irritation.

Adverse Event

An AE is defined as any untoward medical occurrence, regardless of its relationship to the study device or the study procedure. An untoward medical occurrence includes any new, undesirable medical experience

or worsening of pre-existing condition, which occurs at any point from the start of treatment to the final visit.

Expected Morbidity/Anticipated Adverse Events
An expected morbidity/procedural complication is defined as an AE that is known to be common or usual in nature, severity, or incidence during treatment. Post laser vaginal mild irritation is expected and will not be documented as an adverse event unless the investigator considers the pain or fever to exceed that normally anticipated during laser treatment.

Serious Adverse Effect
A serious adverse event is any AE that:

- Led to a death
- Led to a serious deterioration in the health of the subject that either resulted in:
    - A congenital deformity or abnormality
    - A life-threatening illness or injury
    - A permanent impairment of a body structure or a body function
    - In patient hospitalization or prolongation of existing hospitalization
    - Medical or surgical intervention to prevent life threatening illness or injury; or permanent impairment of a body structure or a body function

Note: "Death" should not be reported as an AE. The cause of death should be reported as the AE. The only exception is "Sudden Death" when the cause is unknown.

Adverse Device Effect
An adverse device effect is any untoward and unintended response to a medical device. This includes any event arising from insufficiencies or inadequacies in the instructions for use or the deployment of the device. It also includes any event that is a result of user error.

Serious Adverse Device Effect (SADE)
A serious adverse device effect is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event or that might have led to any of these consequences if suitable action had not been taken or intervention had not been made or if circumstances had been less opportune. Note: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report.

Severity of Adverse Effect
It is the investigator's responsibility to assess the severity of an AE. A change in severity may constitute a new reportable AE.

The following guideline should be used to determine the severity of each adverse event:

- Mild: awareness of experience, but easily tolerated. No medical intervention required.
- Moderate: enough discomfort to interfere with usual activities. Medical Intervention required.
- Severe: inability to carry out usual activities. Medical intervention (including hospitalization or prolongation of hospitalization) required

Relationship of Adverse Events
It is the investigator's responsibility to assess the relationship of an AE to the study procedure and study device.

The following guidelines should be used in determining the relationship of an adverse evet to the study device, study procedure, or other causality:

- NOT related: the event is due to extraneous causes
- Possibly related: The event is unlikely associated, but another cause cannot be ruled out with certainty
- Definitely related: the event is associated with a high degree of certainty
- Unknown: the event cannot be defined by the categories listed above

Reporting Adverse Events
Investigators are required to report all AEs experienced by subjects from the time of enrollment until the subject completes the study or terminates early. All AEs, regardless of their relatedness to the study device must be reported. The investigator will evaluate the intensity of the event, severity of the event, and its relatedness to the study device or procedure. All AEs must be followed until resolution or until they become stable.

Confidentiality
The information from the study will be kept confidential and managed according to the requirement of HIPAA. Only the investigators of the study will have access to the data.

Study Monitoring, Auditing, and Inspecting
The investigator will permit study-related monitoring, audits and inspections by University of South Alabama IRB, and allow the sponsor and government regulatory bodies to study all related documents.

Budget
This is a non-funded project

References
Mauskar, M. M. (2021). Fractionated Carbon Dioxide Laser for the Treatment of Vulvar Lichen Sclerosus. *Obstetrics & Gynecology, 137*(6), 965-967. doi:10.1097/aog.0000000000004414

Ferrara, F., Filippi, F., Messori, S., Iommi, M., Patrizi, A., D'Antuono, A., . . . Bardazzi, F. (2021). Fractional CO2 laser and vulvar lichen sclerosus: An alternative resource during maintenance therapy? A prospective study. *Italian Journal of Dermatology and Venereology*. doi:10.23736/s2784-8671.21.07066-3

Pagano, T., Conforti, A., Buonfantino, C., Schettini, F., Vallone, R., Gallo, A., . . . Sopracordevole, F. (2020). Effect of rescue fractional microablative CO2 laser on symptoms and sexual dysfunction in women affected by vulvar lichen sclerosus resistant to long-term use of topic corticosteroid: A prospective longitudinal study. *Menopause, 27*(4), 418-422. doi:10.1097/gme.0000000000001482