Protocol

Laser hair depilation in adolescents with pilonidal disease, a pilot study and randomized control trial

An investigator-initiated study at Nationwide Children's Hospital

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1. Background Information and Rationale

1.1 Introduction

Pilonidal disease is a common problem among adolescents and young adults. It affects 26 per 100,000 people with an incidence of 1.1%.[1,5] It is characterized by the development of epithelialized tracks and sinuses within the natal cleft extending up to the level of the coccyx posteriorly (the area between the buttocks and posterior to the anus). Entrapped hair follicles become infected resulting in acute and chronic wounds and draining sinuses that can incur both short term and long term morbidity, disability, and poor quality of life.[2] The most often seen initial presentation is that of a painful mass in the sacrococcygeal region.[7] Initial treatment is usually with antibiotics and/or surgical incision and drainage of the inflamed and often infected cystic cavity. Recurrence rates have been conservatively reported at 16% and as high as 30% in some patient populations.[2,3]

The morbidity of this disease is very significant. Patients, usually in their adolescence and young adulthood, may endure chronic pain/inflammation, drainage of sinus tracts associated with significant odor, and occasional negative-pressure wound VAC dressings which are cumbersome. When disease is active, these patients must lay prone at all times when attempting to sleep and are unable to sit due to their wounds; patients with recurrent disease report losing months to years of school and work obligations related to the treatment and chronic nature of their wounds as well as the emotional toll related to an embarrassing problem in a sensitive body area. This disease remains a source of frustration for patients and their families; they desire a durable treatment.

For patients with recurrent disease, there are both medical and surgical methods to treat and/or palliate pilonidal disease. Each of these methods incurs a different risk-benefit profile and has been associated with significant morbidity. Overall, surgical methods appear to be more durable with long term success rates ranging from 84 to 89% However, surgical excision and reconstruction of this area can be associated with significant morbidity and cost. Recurrence rates of pilonidal disease after resection have been reported to be 11%, respectively.[2,3] Furthermore, wound issues after resection with primary closure have been reported to be as high as 30%.[4] Medical therapy is largely dependent upon continued lifelong hair removal either from shaving or chemical depilation, meticulous hygiene to the area, and recurrent courses of antibiotics with intermittent need for both office-based, and operating room incision and drainage procedures. This approach to pilonidal disease incurs a chronicity that can lead to longer term disability and reduced quality of life. In fact, the presence of pilonidal disease and its complications is an accepted indication for Disability Insurance qualification.[6] It has been noted by several authors that an optimal treatment for pilonidal disease has yet to be identified.[2,3]

A small number of studies indicate that laser hair depilation of the natal cleft appears to be protective for pilonidal disease recurrence.[4] Due to this limited data, the mechanism of this disease, and the absence of randomized controlled data in the alternative treatment modalities of pilonidal disease, we believe that laser depilation should be studied as a first line therapy. The goal of this study is to: 1) assess the safety and patient tolerance of laser depilation through a single arm pilot study, and 2) determine the efficacy of this treatment in a single center

randomized controlled trial comparing laser depilation to standard of care in pediatric patients with pilonidal disease.

1.2 Relevant Literature and Data

Surgical Management of Pilonidal Disease: Studies related to the surgical management of pilonidal disease have largely focused on the technical aspects of resection and reconstruction. Over one hundred studies in the literature have reported various methods for managing this disease, but with inconsistent methodology and consistently unsatisfactory outcomes. The ideal operation for pilonidal disease should eradicate the disease, minimize recurrence, and carry low morbidity and disability. Incision and drainage has been the primary treatment in cases of acute presentation. After incision and drainage overall successful healing has been reported to be approximately 60%, whereas the remaining patients required an additional excision procedure before closure of these wounds. For patients with recurrent disease, wide local excision with primary or secondary closure, with consideration of off-midline closure, has been widely advocated. However, wide local excision in this body region is associated with significant morbidity including a post-operative wound complication rate of 30%. Marsupialization for pilonidal disease entails incising the sinus tracts without excision of normal tissue resulting in smaller wounds, limited tissue trauma, and shorter recovery.[8] However, reported duration of healing and durability has been variable.

Medical Management of Pilonidal Disease: Standard medical management of pilonidal disease utilizes hair depilation and local wound care with intermittent antibiotic administration for flares.

Phenol solutions have also been tried in an attempt to sclerose sinus tracts. This involves one or more injections into the affected chronic sinus tracts until filled, removal of sinus hairs and debris with forceps, as well as local shaving. Smaller prospective series have demonstrated success rates ranging from 60% to 95%.[9-12] In cases of recurrent chronic sinus disease, phenol injection and local depilatory cream application on a weekly basis have shown low subsequent recurrence rates (0%–11%) at extended follow-up.[13] In chemical depilatory creams, common active ingredients are calcium thioglycolate or potassium thioglycolate, which breaks down the disulfide bonds in keratin and weakens the hair so that it is easily scraped off where it emerges from the hair follicle. The hair follicle does remain with hair regrowth noted in 2 to 5 days and there can be some local skin irritation on the site of application. Some studies have explored the utility of certain skin glues to close the chronic tracts associated with chronic pilonidal disease. One such study utilized Fibrin glue been injected into these chronic tracts after simple curettage with some positive effect.[14] Overall, studies of sclerosing agents and glue have yielded variable results with limited long term efficacy.

Laser Depilation in Pilonidal Disease: In several retrospective studies and small prospective studies, laser hair removal has shown promise as an adjunct therapy to decrease recurrent infections and decrease the need for repeat surgery in adults and older adolescents. Lukish et al published a retrospective review of twenty-eight teenage patients with pilonidal disease who underwent initial surgical excision of their presenting abscess. Laser depilation was found to be well tolerated with only one patient presenting with recurrent disease after a mean follow up of 24 months.[4] Landa et al determined that their series of 6 patients with recurrent pilonidal disease

saw progressive resolution of folliculitis after 3 to 11 treatments with no need for recurrent excision. No complications or recurrence were reported.[17] Schulze et al reported their experience of eighteen men and five women treated with laser depilation from 2001 to 2004. All patients had experienced recurrent folliculitis and had undergone some form of drainage procedure or prior excision. After surgical excision of the affected area, a Vasculite Plus laser was used for the depilation treatments. Each session involved 9 to 12 treatments and the patients underwent an average of two sessions. All 19 of the patients that remain in follow-up report no recurrence of their folliculitis or need for further surgical procedures.[16] These studies show a positive effect with laser depilation in combating recurrent disease. However, there remains a paucity of prospective controlled studies related to this treatment modality with minimal data reported on the effectiveness of laser depilation in children with pilonidal disease. A prospective study of laser hair removal in pediatric patients to assess safety and generate estimates of effectiveness is warranted.[15-17]

2. Study Objectives

2.1 Primary Objective

This is a two-phase study:

(1) Phase One: Determine the safety and tolerance of laser hair depilation of the natal cleft in adolescents with pilonidal disease.
(2) Phase Two: Perform a randomized controlled trial of laser hair depilation + chemical/mechanical depilation versus chemical/mechanical depilation only to determine outcomes related to recurrence. Recurrence is defined as a new development of pilonidal abscess, folliculitis, or draining sinus after treatment which would require antibiotic treatment, additional surgical incision and drainage or excision.

2.2 Secondary Objective

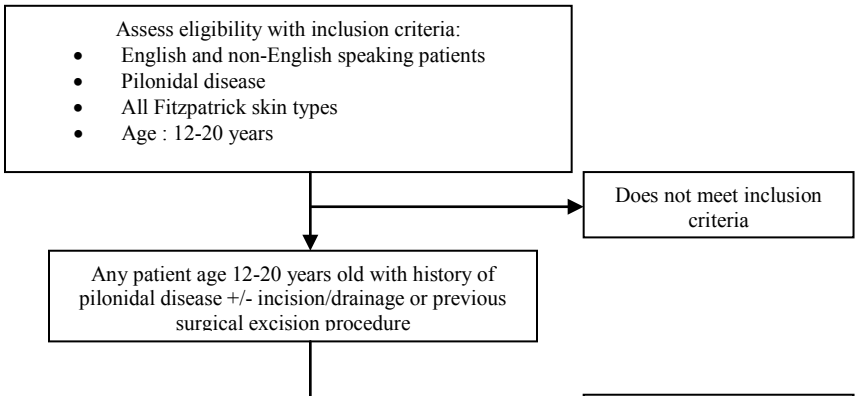
The secondary objective is to compare adverse outcomes, length of stay, days to return to school or work, costs of care and quality of life measures between those that receive laser hair depilation and those that receive mechanical/chemical hair depilation and hygiene recommendations.

3. Investigational Plan

3.1 Study Design

This is a prospective, randomized single-site trial measuring the safety and feasibility of treating children (12-20 years old) with pilonidal disease using laser hair depilation. There will be two cohorts; those who receive laser hair depilation treatments and those that receive only chemical/mechanical depilation. There will be two phases: Phase One – Pilot study to measure safety and tolerance and Phase Two – Randomized control trial to determine efficacy as a treatment of pilonidal disease and as a possible treatment to intervene on future recurrence.

Enrollment:



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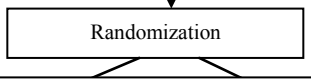

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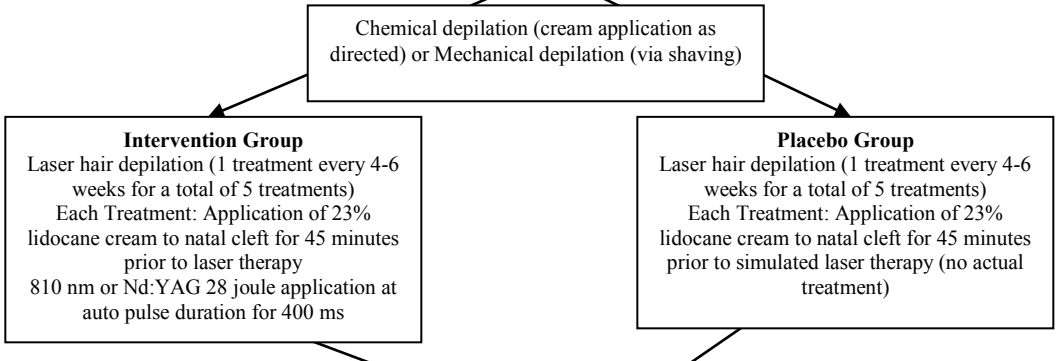
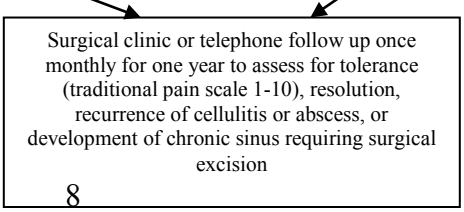


Follow-up:



3.2 Study Duration and Enrollment

3.2.1 Duration of Study and Enrollment

Each patient will be involved in the study for one year. Patients will be brought into Surgery clinic for 1 treatment every 4-6 weeks to obtain a total of 5 treatments. Follow up will occur monthly for one year from the time of initial treatment as we evaluate for tolerance and efficacy.

3.2.2. Total Number of Subjects Projected and Site

A total of 10 children are projected to be enrolled in the first phase of this pilot study. A total of 164 patients are to be enrolled in the second phase of this study. The study will be conducted at Nationwide Children's Hospital (NCH). Study participants will be recruited in Surgery clinic.

Follow-up research visits will be conducted either by phone, at the Surgery clinic of Nationwide Children's Hospital (NCH), or at the Center for Surgical Outcomes Research (CSOR) within the Center for Innovation in Pediatric Practice (CIPP) at the Research Institute at Nationwide Children's Hospital (RINCH)**.**

3.3. Study Population

Children between the ages of 12-20 who are diagnosed with pilonidal disease will be screened for eligibility.

3.3.1 Inclusion Criteria

- English and non-English speaking patients
- All Fitzpatrick skin types
- Age : 12-20 years
- Diagnosis of pilonidal disease

3.3.2 Exclusion Criteria

- History of photosensitivity
- Actively inflamed pilonidal sinus

4. Study Procedures

Screening and Enrollment

During initial contact with a potential subject, a physician-member of the surgical clinic team will assess their eligibility through satisfaction of both inclusion and exclusion criteria. If all eligibility criteria are met, a physician-member of the research team will invite the child and legal guardian to enroll. The physician-member of the research team will then review the written information about the study and answer any questions.

Upon enrollment, study staff will be contacted by the physician-member of the research team who obtained consent/assent. The study staff will then conduct all data collection throughout the study.

Study Procedures: Laser Hair Depilation Group

Treatment Algorithm

Laser group: Once randomized to the laser depilation arm, patients will be brought into Surgery clinic for 1 treatment every 4-6 weeks to obtain a total of 5 treatments. The treatment will consist of an 810 nm (for Fitzpatrick skin types I-IV) or Nd:YAG (for Fitzpatric skin types V-VI) 28 joule application at auto pulse duration for 400 ms as based on Fitzpatrick skin type classification to be assessed prior to the first treatment visit and confirmed by the trained laser technician. A cooling platform and application of 23% lidocaine cream applied 45 minutes from the treatment will minimize any discomfort associated with the heat of the laser treatments.

Control group: They will also arrive at the surgery clinic to have this body area shaved and will receive an application of 23% lidocaine cream applied 45 minutes before their simulated laser treatment. They will then receive a simulated laser treatment in which the laser is maneuvered as usual but not actually fired. This will allow patients to be blinded to their treatment. If at the end of the trial, laser depilation is shown to be effective, patients randomized to placebo will be offered laser therapy at the conclusion of the trial at no charge.

Topical Anesthetic:

Application of 23% lidocaine cream applied approximately 45 minutes prior to the laser depilation treatments. This will aid in the subsequent tolerance of the laser treatment.

Laser Depilation: The two lasers that will be used in this study (810 nm or Nd:YAG) are both FDA approved for hair removal in all areas of the human body including the back. These lasers are being used for hair removal in the back region for which they have FDA approval; however

they do not have specific approval for pilonidal disease. In discussion with Chris Shilling, Director of the Drug and Device Development Services at the RINCH, we believe that an IDE is not necessary for this study as we are using an approved device for investigational purposes with non-significant risk. Laser use in this study poses minimal risk to the patient and these minimal risks are similar to the risks associated with hair removal in the back and other regions of the body for which devices are already FDA approved.

Follow-Up:

Initial follow up for the laser depilation group will be performed to assess for tolerance of the laser treatment. This will occur via use of a REDCap database system where patients can report their pain every 6 hours (with the exception of the overnight period from 8pm-8am) for the first 48 hours after their laser hair depilation treatment. Text message reminders will be sent to these patients for them to give us their pain scores. For those with smart phones, we can text them the link to their REDCap survey, and for those without smart phones or without consistent access to the interne, we can receive their pain scores via return text messages from them. Once tolerance is established, patients will return to surgical clinic every month for their laser or placebo visit. After the 5th clinic visit, they will receive a telephone call monthly to assess for any evidence of resolution or recurrence of disease up to 1 year after the completion of the treatments.

5. Statistical Considerations

5.1. Primary and Secondary Endpoints

Primary endpoints would be the tolerance of the laser depilation treatments based on a pain score consistently <4 and no occurrence of deep second degree burns. These endpoints will be assessed within the first week after each treatment. Secondary endpoints include clinical improvement of pilonidal inflammation and drainage. For Phase Two, the primary endpoint will be the rate of recurrent pilonidal disease at 1 year.

5.2. Statistical Methods

The means/medians and standard deviations/interquartile ranges of the prognostic variables will be evaluated in the total study sample and will be compared between groups (in the phase 2 study) using t-tests or Mann Whitney U tests for continuous variables and chi-squared tests for categorical variables. For the primary outcome of recurrence within one year, we will calculate this proportion and its 95% confidence, based on the exact binomial distribution, in the laser hair depilation group (in the phase 1 study), and we will calculate this proportion and its 95% confidence in both treatment groups (in the phase 2 study) and compare this proportion between groups using a Fisher exact test. SAS version 9.3 (Cary, NC) and Stata version 12 (College Station, TX) will be used in the statistical analyses.

5.3. Sample Size and Power

We anticipate a group of 10 patients to measure laser depilation tolerance. If tolerance is good (>95% the phase 1 patients pain scores < 4 with no deep second degree burns), we will proceed to the phase 2 study. The sample size for phase 2 will be 164 patients. Since the predicted recurrence rate in the control group based on previous studies may be 20% and in the laser group

will be 5%, we would need 82 patients in each treatment group in order to detect this difference at a one-sided alpha of 0.025 using a Fisher exact test.

6. Study Administration
Phase One: Pilot Study

6.1. Data Collection and Management

Patient data such as age, gender, skin type, length of disease, past medical/surgical history, number/date of treatments, treatment parameters, patient pain scores after laser treatments and within the first 12 hours after treatment, and any subsequent episodes of folliculitis/drainage. This information will be kept by the study team and access restricted to the study team.

6.2. Regulatory and Ethical Considerations

6.2.1. Risk Assessment

Patients will be evaluated for their skin type to ensure adequate treatment across the categories.

Laser Depilation Group

Potential risks may include:

- No relief of symptoms
- Recurrence of pilonidal abscess or wound complication
- Photosensitivity or discomfort from laser treatments
- Lastly, loss of confidentiality could be a risk.

No Laser Depilation group

- Loss of confidentiality could be a risk.

6.2.2. Potential Benefits of Trial Participation

Laser Depilation Group

Potential benefits may include:

- Faster relief of symptoms (ex: resolution of pain, erythema)
- Avoiding surgery altogether
    - No risk of surgical complications
- Possible decrease in folliculitis or recurrence

No Laser Depilation Group

- Possible decrease in folliculitis or recurrence due to better hair removal from multiple clinic visits

6.2.3. Risk-Benefit Assessment/Risk Minimization

Laser Depilation Group

Potential benefits include a decrease in the likelihood of recurrent pilonidal disease. The likely risk are pain or burns from laser treatments which will be minimized by applying topical anesthetics and using skin type specific lasers with graded increases in applied power.

6.2.4. Data safety and monitoring

Tolerance to the laser treatments will be monitored closely, especially in the first 48 hours of the laser hair depilation treatments. Treatments will stop at any point in which the patient reports enough discomfort to terminate therapy. Areas treated will be observed for cutaneous changes including excessive erythema, discoloration, or tenderness. Data will be monitored by research team members daily. They will ensure that all data (clinical data and questionnaires) collected are correctly completed. Any suggestion of an adverse event identified by this person will be discussed with the principal investigator immediately.

6.2.5. Adverse events (AE) and Serious adverse events (SAEs)

Any adverse events such as an inability to tolerate the laser therapy or a recurrence will be tracked. Since recurrence is an expected adverse event it will not be reported; however it will be monitored and if we detect an increased rate of recurrence with laser therapy, this will be reported and the trial will be stopped. Mild to moderate pain (pain score 7 or lower) secondary to laser therapy is also consider an expected adverse event and will not be reported. SAEs due to laser treatment include severe pain (pain score 8 or higher) and deep second degree burns.

It is also possible that AE might occur that are not directly related to the study. As such, all AE will be classified as not related (clearly unrelated to study participation), possibly related (temporally related to study participation but could have been caused by other factors), or probably related (temporally related to study participation and cannot be reasonably explained by other factors) to study participation. The clinical study team will review all AE as they occur and determine the seriousness and relatedness of them.

We do not expect any severe AE in either study group. The clinical study team will review any SAE as they occur. All SAE deemed probably related to the study (and all deaths) will be reported to the IRB within 72 hours of discovery.

6.3. Recruitment Strategy

Patients who present to Pediatric Surgery clinic will be approached to evaluate whether they would be interested in taking part in the study. In addition, patients admitted after initial surgical drainage of a pilonidal abscess will be approached to evaluate whether they would be interested in taking part in the study Risks and benefits would be explained, informed consent and assent will be obtained, and we would schedule the patient for their first treatment.

6.4. Informed Consent/Assent

All informed consents and assents will be performed by a physician-member of the research team.

If the child and legal guardian (for subjects < 18 years) are interested in participating in this study, a physician-member of the research team will guide the child and legal guardian through the informed consent/assent process. Written informed consent will be obtained from one legal guardian of subjects < 18 years of age and from the patient him or herself if he or she is ≥ 18 years of age. Written informed assent will be obtained from subjects ≥9 and < 18 years of age.

Refusal to participate in the study will not affect the child's clinical care. Participants and their legal guardian have the right to switch to the standard treatment and/or withdraw from the study at any time. Withdrawal from the study will not affect receipt of clinical care.

6.5. Payment to Subjects/Families

Laser depilation treatments will be provided at no cost to the patient. All clinic visits and medications related to the study will be provided at no cost to the patient.

6.6. Confidentiality

Privacy and security will be maintained by minimizing the amount of identifiable data as much as possible. Only study identifications (IDs) will be used to identify patients on all data forms and all datasets used for analysis. The file linking study IDs to patient names and medical record numbers (MRNs) will be password protected and will not be made available to non-study staff or used during data analysis. All study information will be compiled in REDCAP, to which only study staff will have access.

Phase Two: Randomized control trial

7.1. Data Collection and Management

Patient data such as age, gender, skin type, length of disease, past medical/surgical history, number/date of treatments, treatment parameters, patient pain scores after laser treatments and within the first 12 hours after treatment, and any subsequent episodes of folliculitis/drainage. This information will be kept by the study team and access restricted to the study team.

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9. Appendix:

Pain Scales used:

http://anchor.columbuschildrens.net/pain-management-assessment-directory

Visual Analog Scale (VAS) (8 years of Age and Older)

On this chart the "0" means no pain, each number means a little more pain, and "10" means the most pain possible.

No pain Terrible pain

QIS-6 Pain Management Scale 4/04

All of the different scales are described and examples are available at the above website (FLASS, FACES and VAS).

Fitzpatrick Skin Types:

The Fitzpatrick Classification

	Skin Type	Skin Color	Characteristics
Higher Risk	I	White; very fair; red or blond hair; blue eyes; freckles	Always burns, never tans
	II	White; fair; red or blond hair; blue, hazel, or green eyes	Usually burns, tans with difficulty
	III	Cream white; fair; any eye or hair color; very common	Sometimes mild burn, gradually tans
Lower Risk	IV	Brown; typical Mediterranean Caucasian skin	Rarely burns, tans with ease
	V	Dark Brown; mid-eastern skin types	very rarely burns, tans very easily
	VI	Black	Never burns, tans very easily

Fitzpatrick TB: Soleil et peau. J Med Esthet 1975;2:33034

Physician Informed Consent Script:

Good morning/afternoon. My name is Dr. _____. I work with Dr. Katherine Deans and Dr. Peter Minneci at the Department of Surgery at Nationwide Children's Hospital. I know that your child has been seen here at Nationwide Children's Hospital for his/her pilonidal disease. We are doing a research study that is examining a possible treatment which might be successful in treating this problem. I'd like to tell you about our research study on the use of laser hair removal in pilonidal disease. May I tell you more about this?

{If Yes}

As surgeons, we all have different beliefs on how to best treat pilonidal disease in adolescents and young adults. Some surgeons believe that surgery to remove the infected tissue is the best way to treat this disease. There is evidence that the cause of this problem may be related to infected hair follicles in this body area which become long term infections over time. So we are conducting a study to investigate whether using laser hair removal treatments is a successful way to treat the problem as it develops and also help prevent this problem from returning.

In this pilot study, we are seeing how well patients tolerate laser hair removal treatments. Let me explain the risks and benefits.

Risks of laser hair removal for this problem include the following:

- No relief of symptoms
- Return of pilonidal disease
- Discomfort from laser treatments

Benefits of laser hair removal for this problem include the following:

- Possible faster relief of symptoms (ex: resolution of pain, redness)
- Avoiding surgery altogether
- No risk of surgical complications
- Possible decreased risk of return of the pilonidal disease

Please remember that your participation is voluntary and you can decide not to be in the study at any point. I will now explain what you can expect as a patient. When coming in for your treatment appointment, we will bring you to the exam room. There, we will shave the pilonidal area and apply a lidocaine anesthetic (numbing) cream on your skin which will remain there for about 45 minutes. After this, we will then use the laser on the area. This process should only take a few moments. Please tell us if you feel any pain during or immediately after the treatment. After your visit, please let us know (via text or email) your pain score from 1-10 (10 being the highest level of pain) at 6, 12, 18, and 24 hours after your treatment visit.

What questions may I answer for you?

Would you be willing to take part in this study?

{No - Thank you for your time.}
{Yes - Excellent. Thank you for your participation.}

Our number is (614) 722-0742; it will be on the bottom of the emails that you receive from us. Please do not hesitate to call with any questions or concerns.
I will meet with you when you come here to review our consent form on paper and I will give you a copy of the form.

Follow up Data Collection Forms:

Name:	Pain Score Report: 6 Hours Post-Treatment (1-10)	Other concerns:
Date:		

Name:	Pain Score Report: 12 Hours Post-Treatment (1-10)	Other concerns:
Date:		

Name:	Pain Score Report: 18 Hours Post-Treatment (1-10)	Other concerns:
Date:		

Name:	Pain Score Report: 24 Hours Post-Treatment (1-10)	Other concerns:
Date:		

Name:	Pain Score Report ___ Month(s) Post-Treatment	Number of laser treatments to date	Erythema	Drainage	Other concerns
Date:					

Initial Data Collection Sheet:

Name	MRN	Gender	Age	Height (cm)	Weight (Kg)	Race	Fitzpatrick skin classification (I-VI)	Date of initial diagnosis	Date of initial Incision and Drainage or Antibiotic Treatment	Date of previous surgical excision procedure	Randomization Group (laser hair depilation vs. placebo)	Laser type used (Nd:YAG or 810 nm)	Number of laser treatments	Time since last laser treatment (Weeks)	Recurrent folliculitis present at any follow-up? (Y/N)	Adverse events (photosensitivity, irritation from depilation methods, etc.)	Pain score Immediately after treatment (1-10