Tripler Army Medical Center

Honolulu, Hawaii Home of the Pacific Regional Medical Command

HOME

STUDY OUTLINE

REFERRAL PROCESS

BROCHURE

SHAVING INSTRUCTIONS

CONTACT INFORMATION

PFB REGULATIONS

BEFORE / AFTER PHOTOGRAPHS

PFB HOME PAGE

TAMC Map & Phone Numbers

AMEDD Page

Army Page

LASER HAIR DEPILATION FOR THE TREATMENT OF PFB USING THE CANDELA GENTLE YAG™ 1064nm ND-YAG HAIR REMOVAL LASER STUDY # TAMC 24H03

PROVIDER INFORMATION

A total of 54 weeks is needed to complete the study.

All subjects will receive six laser treatments at either three week or six-week intervals.

Approximately 2 hours will be needed at each treatment session to include:

1. Evaluation of papule counts, severity scoring and evaluation for potential side effects from previous treatment: 15 minutes.

2. Digital photographs of areas: 10 minutes.

3. Application of topical anesthesia: Left in place for 60 minutes after application and will be removed just prior to receiving laser treatment.

4. Laser procedure: 15-20 minutes.

5. Postoperative evaluation and application of anti-inflammatory cream: 2-3 minutes.

6. Application of ice pack to postoperative treatment areas: 15 minutes duration.

7. After completing the 6th treatment, subjects will follow-up for two re-evaluations at the third and sixth month. Follow-up evaluations involve:

WHAT WILL BE DONE:

The GentleYAG™ Hair Removal Laser used in this study produces an intense light that can selectively destroy or damage hair follicles while minimizing the effects to the surrounding skin. The hair removal laser works by targeting the pigment within the hair follicle. The targeted pigment within the hair follicle is only present when the hair is in a “growth phase” meaning that 30% of the hairs will be unaffected at any given single treatment requiring multiple treatments. The FDA has approved The GentleYAG™ laser for “permanent hair reduction.” Permanent hair reduction is defined as elimination of hair growth or a long interval (greater than six months)

before hair begins to regrow.

1) The Principal Investigator will examine the subject's health records and shaving profile. Documentation will also be screened using the established inclusion / exclusion criteria. Subjects meeting the inclusion criteria will then be consented and scheduled for treatment. Pre/postoperative care and shaving instructions will be provided and reviewed at the time of evaluation.

2) Subjects will have baseline digital photographs taken and at each treatment / evaluation period. Subjects will be assigned a predestinated study ID# that randomly, similar to flipping a coin, assigns them to one of two treatment interval groups (3 or 6 weeks). Subjects will have a 50/50 chance of being assigned to either the 3 weeks interval group or the 6 weeks interval group.

3) Subjects will be required to shave for seven consecutive days prior to each treatment and will begin to shave daily after completing their 6th treatment. Subjects will maintain their no shaving profile until the completion of the sixth treatment. Standardized shaving instructions will be given to each subject. Subjects will be provided and use the following items as directed:

Bump Fighter Razor® American Safety Razor Company

Bump Fighter Cartridge Refill Pack® American Safety Razor Company

Bump Fighter Shaving Gel® American Safety Razor Company

Cetaphil Cleanser® Galderma Laboratories, Inc.

4) Subjects will have Topicaine® Gel ESBA Laboratories, a topical anesthetic cream, applied to the treatment areas for 60 minutes prior to each treatment. Treatment areas will involve both the face and neck. Areas will be divided into five sections: right cheek, left cheek, chin, right neck, and left neck. The Topicaine will be removed just prior to being treated with the laser. A single application of a topical steroid cream (Temovate®) will be applied immediately after the laser treatment to help reduce inflammation (redness or swelling).

5) All subjects will have six treatments using the hair removal laser every three or six weeks (as assigned). You will be asked to rate the amount of discomfort (using a 10 point scale) at the end of each treatment session.

6) All subjects will resume shaving at the completion of the sixth treatment. Subjects will be given a shaving log. Subjects will document everyday that they shave and will rate any occurrence of irritation on a 1-4 scale. Subjects who rate their irritation as moderate or severe will be instructed to contact the Principal Investigator who will evaluate them within 48 hours of being notified.

7) Papule and pustule counts / severity scores will be assessed and recorded at three and six months thereafter using a standardized scale. Subjects that develop significant side effects or develop moderate to severe irritation once they resume shaving, will contact the Principal Investigator and will be evaluated within 48 hours of being notified.

8) Subjects who do not achieve and maintain an 81 to 100% resolution compared to their baseline evaluation will be classified as a treatment failure. Subjects who maintain an 80% or greater reduction of symptoms compared to the baseline evaluation will have a *recommendation* made to their commanding officer to have their "non shave profile" status changed.

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