Efficacy and Safety Evaluation of Splendor-X SMART System for hair removal

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29490

Source
NTR

Brief title
TBA

Health condition

Excessive hair growth, hirsutism

Sponsors and support

Primary sponsor: Lumenis Ltd.
Source(s) of monetary or material Support: Industry (Sponsored by Lumenis Ltd.)

Intervention

Outcome measures

Primary outcome

Feasibility of hair removal treatment with the Splendor-X SMART laser platform for hair removal treatment for all skin types.

Secondary outcome

• Percent change of number of hairs before and after 3 treatments with the Splendor-X SMART system as compared to Splendor-X.
• Difference between the Splendor-X SMART system and the subjective physician judgment on standard assessments of skin characteristics.
• Splendor-X SMART melanin and erythema measurements as compared to MX18 for each treatment.

Study description

Background summary

It is a Prospective Multi Center Feasibility study, Within-Subject Controlled Treatment in healthy subjects. Subjects will receive 3 treatments and will return for two follow-up visits. Each treatment will include at least 2 different anatomical areas comparing each one in a left/right side to side comparison for 1) Splendor-X standard treatment: the investigator will choose his/her own laser presets to treat the subject with and 2) Splendor-X SMART treatment: the Splendor-X SMART system will calculate the recommended laser presets for optimal safety and efficacy parameters.

Study objective

We assume that hair removal treatment with the Splendor-X SMART is feasible.

Study design

Screening visit max 14 days before treatment 1, treatment 1, treatment 2 at 6 to 8 weeks after treatment 1, treatment 3 at 6 to 8 weeks after treatment 2, follow-up visit 1 at 3 months after treatment 3, follow-up visit 2 at 6 months after treatment 3.

Intervention

The study includes a total of up to 6 visits: 1 screening visit, 3 treatment visits and 2 follow-up visits.

Contacts

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Eligibility criteria

Inclusion criteria

1. All skin types: I-VI
2. male or female
3. Age – 18-50 years of age
4. Having two suitable treatment areas (legs, thighs, back, Chest, axillae, bikini, front of the neck or abdomen) with dark brown or black hair appropriate for hair removal;

Exclusion criteria

1. Previous hair removal procedures at intended areas
2. Active infections in the treated area;
3. Dysplastic nevi in the treatment area;
4. Significant concurrent skin conditions or any inflammatory skin conditions;
5. Active cold sores, open lacerations or abrasions in the treated area;
6. Chronic or cutaneous viral, fungal, or bacterial diseases;
7. Intense tan, Deep suntan, recent suntan within 2 weeks, sunburn or artificially tanned skin;
8. Current cancer, history of skin cancer or pre-cancerous lesions at the treatment areas;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
The data that is collected during the study (age, gender, skin type, information about the subject's health, concomitant medication and (medical) information) including the photographs that may be used as part of publication. In addition, the data including the photographs can be used for ongoing research related to this study, other research, education, or information purposes. To protect the subject's privacy, the data will receive a code which will be used in the reports and publications about the study.
The information and the key to the code will be stored at the clinical study site and may be transferred for the purpose of processing, analysis etc. to associated researchers outside the European Economic Area. This transfer will be done according to the European General Data Protection Regulation 2016. The data will be stored for 15 years at the hospital and for 15 years with the Sponsor. The key will not be shared with the Sponsor.
There are some people who will have access to personal information without the code. These people are monitors, Sponsor representative that may be present during procedures, and National and international authorities (for instance the Healthcare and Youth Inspectorate of the Netherlands). These people will keep the subject's information confidential.

Ethics review

Positive opinion

Date:	04-08-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9651
Other	METC AMC : 2021_026

Study results