Efficacy and Safety Evaluation of Splendor-X SMART System for hair removal, Prospective Multi Center Feasibility study, Within-Subject Controlled Treatment in healthy subjects.

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Primary Objective: To study feasibility of a novel Splendor-X SMART system platform for hair removal treatment for all skin types. Secondary Objectives: To study efficacy and safety of the Splendor-X SMART system for hair removal treatment for all…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52239

Source
ToetsingOnline

Brief title
Feasibility, Safety and Efficacy of the Splendor-X SMART for hair removal

Condition

- Other condition

Synonym
Excessive hair growth, hirsutism

Health condition

Overmatige haargroei

Research involving
Human

Sponsors and support

Primary sponsor: Lumenis Be Ltd.
Source(s) of monetary or material Support: Lumenis Ltd

Intervention

Keyword: Artificial intelligence, Hair-removal, Laser, Skintypes

Outcome measures

Primary outcome

Parameters

Feasibility studies are usually not powered as the number of participants is not critical - but obviously: the more, the better. Power calculations for demonstrating efficacy are below.

Outcomes:

Primary Endpoint

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

Treatment with the Splendor-X SMART system will be consider as feasible when a full treatment is completed using the calculated recommended laser presets by the AI system (preset is not overruled by the physician). The percentage of success will be documented.

Safety endpoints

- Incidence of adverse events during the treatment and follow-up period

- Immediate response (erythema, edema, purpura, etc.) following each treatment measured on a 5-point Likert severity scale.

- Subject*s assessment of pain and discomfort associated with treatments using an 11-point VAS pain score.

Secondary outcome

Secondary endpoints

- Percent change of number of hairs before and after 3 treatments with the Splendor-X SMART guided as compared to the Splendor-X.

- Difference between the measurements from novel Splendor-X SMART system and the subjective physician judgment on standard assessments of skin characteristics (hair color, thickness, density).

- Splendor-X SMART melanin and erythema measurements as compared to MX18 for each treatment.

Study description

Background summary

Laser is the preferred hair removal method due to its superior speed, safety, effectiveness and permanence. Destruction of the regenerative follicular structures is a result of selectively absorbed light (in a specific wavelength, pulse duration, and fluence) in the melanin within the hair shaft and follicle. Therefore, the laser strength depends on the amount of melanin in the epidermis of the skin: the darker the skin the higher the laser strength. However, if the skin surrounding the follicle contains melanin, such as in tanned or dark coloured skin, it may also absorb the photonic energy, resulting in skin damage. To avoid skin damage, the Splendor-X has not only the alexandrite laser at 755nm, successfully used to treat patients of skin phototypes I-IV, but also the 1064nm Nd:YAG laser for treating tanned or darker skinned patients, specifically those with skin phototype VI. Previous studies have shown that multiplex treatments, sequentially using both wavelengths have a favourable side effect profile when compared to single 755nm wavelength treatments.

Assessment of the human skin type is essential for optimal treatment and to avoid damage. Human skin colour span from the darkest brown to the very light hues. The skin colour can also vary within different areas in the same person (e.g. front and back of the hand). Skin type recognition by eye differs significantly from measured melanin level. When physicians are in doubt about the skin type, spectrophotometers are used to measure melanin levels of the skin separately from the laser treatment which significantly enhances accuracy. Spectrophotometer-based assessment of skin type incorporated into the handpiece and consequent automated calculation of the laser pre-set, implemented in the laser system for each laser spot, is therefore the only precise way to accurately adjust the laser parameters to the specific conditions of skin and hair.

To improve the hair removal treatment of the Splendor-X, a new software using artificial intelligence (AI) to determine the ideal laser parameters, is developed. This software is implemented in the Splendor-X SMART, which is a modified version of the CE and FDA proof Splendor-X. The approach to be studied here is the feasibility of the advanced Splendor-X SMART to enable safe and efficient hair removal treatment guided by artificial intelligence (AI).

Study objective

Primary Objective: To study feasibility of a novel Splendor-X SMART system platform for hair removal treatment for all skin types.
Secondary Objectives: To study efficacy and safety of the Splendor-X SMART system for hair removal treatment for all skin types.

Study design

Multi-centre Feasibility study Within-Subject Controlled Treatment in healthy subjects.

Intervention

Within-subject randomization will assign standard treatment or Splendor X SMART AI guided treatment to either left or right half of the anatomical area.

Study burden and risks

Risks
Eye injuries are possible to the operator and to any other entity (including subjects) in treatment room. It should be entirely preventable by proper use of dedicated eye shields, which will be worn by staff/ subjects in the presence of laser irradiation. The laser room should undergo a Laser Safety Review to ensure that local safety standards are followed. The laser rooms are already used for routine laser treatments and are organized according to the Dutch

guidelines for Safe Use of Lasers (Laserveiligheid in de Gezondheidszorg, CJPM Teirlinck en SR Vaartjes, Nederlandse Vereniging voor Klinische Fysica, 2015).
The potential risks for adverse effects of the treatment procedure include but are not limited to hypo or hyper-pigmentation , Pain during treatment, Erythema and edema immediately after treatment, it disappears in a few hours or a few days at most , Crusts effect, Formation of blisters during the treatment, but due to their intra-epidermal nature, they usually heal without producing scars, Scar effect or Poor clinical response, itching, tingling or burning sensation (during or immediately following treatment which might last up to several days), inflammation (caused by possible skin irritation from the shaving/ treatment), development erythema ab igne, a temporary increase in hair growth in the treated area, bruising or a purple discoloration of the treated area (might last for several days), skin burn, infection (infection in the hair follicle/ viral infection).
As detailed above in the Anticipated Adverse Events section. In the case of an infection evolving in the treated area the subject will be provided antibiotics for the treatment of the infection at no cost.
The analyzed safety requirements are considered by the manufacturer as fully mitigated to an acceptable risk level per the standard requirements.
A complementary risk analysis has been performed to assess the possible additional risks related to the modifications that were introduce to the investigational device for the purpose of this study. It has been determined that no additional risks were introduced and all residual risk are considered acceptable.

Benefits
Potential benefits may include but are not limited to temporary hair removal, permanent hair reduction.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy adult, females or males, between 18 and 50 years of age with skin type I-VI, having at least moderately dense dark brown or black hair on at least 2 areas. These treated areas will diverse between anatomical areas: legs, thighs, upper or lower back, chest or abdomen, axillae, bikini, front of the neck.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Splendor X-SMART
Registration:	No

Ethics review

Approved WMO Date:	17-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL76407.018.21
Other	Nog niet bekend - zal voor de start van de studie bekend zijn