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Investigating effects of laser hair removal in people from different ethnic groups

Submission date
25/11/2018

Recruitment status
No longer recruiting

Registration date
27/11/2018

Overall study status
Completed

Last Edited
30/12/2022

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Laser hair removal (LHR) has become one of the most popular treatments in aesthetics (beauty treatments). A diode laser can be used for hair reduction. Side effects are common, therefore managing them is important for every laser practitioner to ensure patients' safety along with achieving the best results. Research shows that laser treatment is effective for hair removal in all skin types according to the Fitzpatrick scale (which divides skin into how easily it burns in the sun), but there is a need to investigate side effects in people of different ethnicities. This study aims to investigate the occurrence and types of side and adverse effects after performing diode laser hair removal in people of various ethnicities including White, Black, Asian and Mixed Race, including participants with all skin types according to the Fitzpatrick scale, and to assess its impact on the results of the treatment measured as a percentage of hair reduction in the treated area.

Who can participate?
Healthy volunteers of both genders, all ethnicities, all skin types, of age 20-40 years.

What does the study involve?
This study involves 6 diode laser treatments in the selected part of the body at 6-week intervals. Hair loss percentage will be measured using before and after photographs, as well as the participant's own estimate of hair reduction. Side effects will be recorded before and after treatment.

What are the possible benefits and risks of participating?
Participants can expect a long-term, stable reduction in the number of hairs re-growing after the course of treatments. Hair reduction would last for 4 to 12 months and permanent hair reduction doesn't mean the elimination of all hairs in the treatment area. The reference point for an excellent result is defined to be an 80% hair loss. There is a risk of side effects, including skin hyperpigmentation, skin redness, skin irritation, skin hypersensitivity, skin burns, discomfort, damage to the natural skin texture, scarring, excessive swelling, blisters and bruising.

Where is the study run from?
Klinika Mlodosci, ul Lakowa 27, Krakow (Poland)

When is the study starting and how long is it expected to run for?
March 2016 to May 2019

Who is funding the study?
The investigator will pay the trial's costs.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016/2019 HR

Study information

Scientific Title
Aspects of diode laser (805 nm) hair removal safety in people of various ethnicities

Study objectives
This study aims to investigate the effects of diode laser hair removal in people of different ethnicities, including its effectiveness in removing hair as well as any adverse events.

Ethics approval required

Old ethics approval format

Ethics approval(s)
University of Physical Education, Krakow (Poland), 28/02/2016. ref: 28022016/2016/2019/HR

Study design
Observational

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Laser treatment of excess hair growth

Interventions
During initial consultations, according to the study protocol and to ensure patients' safety, investigators assess skin types using the Fitzpatrick Scale Quiz. The Fitzpatrick scale is defined as a classification for human skin colour as a way to estimate the response of different types of skin to light exposure. To define ethnicity, ethnic background questions are asked following the Census 2001 scheme acknowledged in the UK, which categorises ethnicity as White, Black, Asian and Mixed-race.
During the initial consultation, practitioners explain a realistic expected outcome of the course of six treatments. Participants are familiarised with the definition of permanent hair reduction issued by the FDA and the possible result of the treatment as a long-term, stable reduction in the number of hairs re-growing after the course of treatments. Participants are aware that hair reduction would last for 4 to 12 months and permanent hair reduction doesn't mean the elimination of all hairs in the treatment area. The reference point for an excellent result is defined to be an 80% hair loss. Participants are aware of side effects and adverse effects possibilities. Before carrying out the treatment, the patient's skin was shaved and cleaned, and during the course of six treatments, the patients are not using any other methods of hair removal, as per the therapist's pre- and post- instructions. All participants sign informed consent for treatment and volunteer for participation in the study, and before each of the treatment medical history is checked and signed by participants.
A skin patch test in the area of the treatment is provided for all participants was included in the study. A diode laser with a wavelength of 805 nm, minimum peak power 2100 W and a pulse duration between 15 and 400 ms, ET sapphire cooling assisted handle 9 x 9 mm large, and pulse energy density between 10 and 100 J/cm2 was used for all treatments. This research protocol adheres to patch test treatment settings such as fluence (J/cm2) and pulse duration (ms) as per

manufacturer's guidelines for different skin type, hair colour, hair texture and modified according to individual skin reactions.
Patch test settings were starting points for treatments. To achieve the best results and to ensure patients safety (and taking into account their ethnic background and medical history) during each treatment, fluence and pulse width is adjusted to the individual participants' skin reaction. Initial settings and final settings of pulse duration (ms) and fluence (J/cm2) were documented for this study.
All participants are subject to six treatments planned with intervals of 6 weeks. Any side effects, adverse effects, other factors which can have an impact to the results of the study were assessed and documented prior to the treatment. Immediate skin reactions were assessed 15 mins after each treatment. 6 weeks after the last (of 6) treatment, participants attend for a last visit to measure endpoints of the course of the treatments and to share their opinion in regards to the satisfaction level.

Intervention Type
Device

Primary outcome measure
1. Objective measurement of hair loss percentage in treatment area assessed by taking photographs with zoom x20 of a 1-cm2 area, 4 cm lower from the middle distance between iliac spines. The number of hairs is counted before the first treatment and 6 weeks after the last treatment.

Secondary outcome measures
1. Subjective assessment of hair loss percentage by participant at 6 weeks after the last treatment
2. Satisfaction level of participant on a 5-point scale
3. Side effects (skin hyperpigmentation, skin redness, skin irritation, skin hypersensitivity, skin burns) assessed before and immediately after each treatment
4. Adverse events (discomfort, damage to the natural skin texture, scarring, excessive swelling, blisters, bruising) assessed before and immediately after each treatment

Overall study start date
31/03/2016

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Aged 20-40 years
2. Undergoing laser hair reduction treatment

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
500

Total final enrolment
217

Key exclusion criteria
1. Any previous laser or intense pulsed light (IPL) treatments in the study area
2. Cancer
3. Use of hormonal drugs, photosensitizing drugs or antibiotics
4. Use of cosmetics containing retinol, vitamins A, E, or C, or fruit acids
5. Intake of herbs that can be photosensitizing
6. Suntan
7. Chemical or mechanical depilation or hair bleaching during previous 6 weeks
8. Irritated skin, dermatosis of various etiology, livedo reticularis or photodermatitis
9. Epilepsy
10. Pregnancy and breastfeeding
11. Isotretinoin use within the past year
12. History of photosensitivity
13. History of hypertrophic scars and keloids

Date of first enrolment
30/01/2016

Date of final enrolment
30/03/2019

Locations

Countries of recruitment
England

Poland

United Kingdom

Study participating centre
5th Avenue Medical Clinic
7 Upper Tooting Rd
London
United Kingdom
SW17 7TS

Study participating centre

Klinika Młodości
ul. Lakowa 27
Krakow
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31-443

Sponsor information

Organisation
Klinika Młodości

Sponsor details
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Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The first analysis results will be published in Lasers in Medical Science.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/03/2020	19/02/2021	Yes	No
Other publications		25/02/2019	30/12/2022	Yes	No