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Does hair removal using intense pulsed light (IPL) devices change the effectiveness of subsequent hair removal using a laser?

Submission date
12/09/2019

Recruitment status
No longer recruiting

Registration date
25/09/2019

Overall study status
Completed

Last Edited
25/09/2019

Condition category
Skin and Connective Tissue Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
As IPL used by professionals and home use devices are very popular authors wants to see if any form of this depilation has an impact on use of diode laser for hair reduction in the future.
This study is designed for healthy females volunteers aged 21-23 with dark, thick hair on their axillas. Participants are going to receive treatments using IPL devices and later on diode laser. Benefits observed are a reduction of numbers of hair on the treatment area. Risk are associated to use of light for hair reduction and could be: burns, pigmentation, scars.
The study is run from Youth Clinic (Klinika Mlodosci) in Krakow, Poland. Study starts on Jan 2017 and ends in October 2019. The study is funded by investigators. Participants are not paid for taking part in this trial but treatment will be given free of charge.

Background and study aims
Intense pulsed light (IPL) is used as a cosmetic treatment to remove unwanted hair or freckles. It is a burst of light at different frequencies, which can be targeted at pigmented cells or hair follicles to destroy them. IPL is used in beauty salons and also in devices for home use. This study aims to investigate when prior use of IPL changes the hair removal and side effects when laser treatment is used subsequently.

Who can participate?
Healthy women aged 21 to 23 years with thick dark hair in their armpits.

What does the study involve?
The participants will receive one, two or three IPL hair removal treatments to one of their armpits, at home or in a beauty salon, and then three laser treatments. The other armpit received three laser hair removal treatments in the salon. Photographs of both armpits will be taken before the start of the treatment and 6 weeks after the end of treatment and the participants will rate their satisfaction with the treatment.

What are the possible benefits and risks of participating?
The participants receive the hair removal free of charge. Light-based hair removal has potential side effects of burns, pigmentation and scars.

Where is the study run from?
Youth Clinic (Poland)

When is the study starting and how long is it expected to run for?

Who is funding the study?
This study is funded by the investigators.

Who is the main contact?
Magdalena Atta-Motte, magda.atta.motte@consultant.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MAMIZ/2019

Study information

Scientific Title
The effectiveness of diode laser epilation following non-coherent light therapy

Study objectives
Investigators during their clinical practice found out that diode laser hair reduction can be affected with use of non-coherent light devices by decreasing its effectiveness. The objective of this study was to compare the results of epilation treatments by laser and by intense pulsed light (IPL) and to rate the effectiveness of diode laser epilation following non-coherent light therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/01/2017, University School of Physical Education (Wydzial Rehabilitacji Ruchowej, Katedra Kosmetologii, Al. Jana Pawla II 78, 31-571 Kraków, Poland; +48 12 683 11 64; izaleska@icloud.com), ref: MAMIZ2017-2019

Study design
Randomised parallel-arm study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hair removal

Interventions
The study was carried out in a clinic in Krakow (Poland). Informed consent for participation and treatment was obtained during the consultation. No hair maintenance was done in the treatment area during the study.

To randomise the participants, 15 encoded group names were thrown into a closed container. After consultation, participants qualified for the study randomly selected one lottery from the container, according to which they were assigned to a specific research group.

The participants were divided into groups:
1. One intense pulsed light (IPL) treatment followed by three diode laser treatments
2. Two IPL treatments followed by three diode laser treatments
3. Three IPL treatments followed by three diode laser treatments
4. One home-used IPL treatment followed by three diode laser treatments
5. Two home-used IPL treatments followed by three diode laser treatments
6. Three home- used IPL treatments followed by three diode laser treatments

Each participant received hair removal treatment in their armpits (axillae) being randomly assigned to the right or left axilla for IPL course of treatments followed by diode laser. The other axilla was treated three times with the diode laser as a control measurement for comparison. The epidermal cooling temperature was also identical at 5°C. The operation room temperature was maintained between 18°C and 20°C. The participants received three, four, five or six treatment sessions at 6-week intervals. In each session, a single pass of IPL or laser treatment was conducted with a 10% overlap between treated areas. All procedures were conducted by a therapist who had ample experience of hair removal. Hair reduction was quantified with high-resolution digital photos (zoom x20) taken shortly before each of the treatments and 6 weeks after the last treatment

The 805 nm diode laser was set up with the following parameters: fluence 32-36 J/cm2, pulse duration 30-100 ms, frequency 2.31-2.54 Hz, 9x9 mm handpiece. The
IPL device was set up with a wavelength of 640-1200 nm, fluence 28-34 J/cm2, pulse duration 5-30 ms. Home use devices of various manufacturers were used. All settings were adjusted according to skin response to the patch test settings

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
1. Number of hairs in each photo was counted by using magnified screen images from photos taken before treatment and 6 weeks after the end of treatment. Three evaluators independently counted the number of hairs and the mean value was used for the evaluation. To keep the evaluators blind, no information was given about the participants, the axillary side, or the chronology of the photographs. Hair reduction from each axilla, the main outcome measure in this study, was defined as the number of removed hairs divided by the number of initial axillary hairs, and expressed as a percentage.
2. Post-procedural assessment was quantified on a visual analogue scale (VAS) ranging from 0 to 3, 6 weeks after the last session where 0 meant thicker hairs, 1 meant no change observed, 2 meant thinner hairs, and 3 meant the hairs were thinner and weaker.

Key secondary outcome(s))
1. Participant's subjective satisfaction scale at 4 weeks after the last treatment, where 1 meant "the treatment did not meet my expectations", 2 meant "lack of satisfaction of the treatment effect", 3 meant "moderate contentment", 4 meant "satisfying effects", and 5 meant "the treatment has met all my expectations".
2. Adverse events were evaluated at each visit by means of physical examination and through the patients' self-report

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. Healthy females
2. Aged 21-23 years
3. Thick, black hairs in axilla
4. No history of use of light-based methods of hair reduction
5. Skin type II-III

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Cancer or history of cancer
2. Use of light based devices for hair removal on axilla
3. History of keloid scarring
4. Active infection or a history of herpes simplex in the treatment area
5. Use of depilatories or other hair removal treatments, such as waxing, plucking or electrolysis, within the preceding 6 weeks
6. Hypersensitivity to hydroquinone or other bleaching agents, if applicable
7. Use of oral Accutane (isotretinoin) within the preceding 6 months
8. Epilepsy or other light-related condition

Date of first enrolment
01/02/2017

Date of final enrolment
10/10/2019

Locations

Countries of recruitment
Poland

Study participating centre
Youth Clinic
Łąkowa 27
Krakow
Poland
31-443

Sponsor information

Organisation
Magdalena Atta-Motte

Funder(s)

Funder type
Other

Funder Name
Investigator funded

Funder Name
Izabela Zaleska

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be included in the subsequent results publication

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