

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

|  |  |  |
|--|--|--|
| <b>Submission date</b><br>25/11/2018   | <b>Recruitment status</b><br>No longer recruiting                | <input type="checkbox"/> Prospectively registered    |
|  |  | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>27/11/2018 | <b>Overall study status</b><br>Completed                         | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>30/12/2022       | <b>Condition category</b><br>Skin and Connective Tissue Diseases | <input type="checkbox"/> 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 Młodosci, 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?  
Magdalena Atta-Motte  
atta.motte@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Magdalena Atta-Motte

**ORCID ID**  
<http://orcid.org/0000-0001-7374-1617>

**Contact details**  
21 Kings Avenue  
Carshalton  
United Kingdom  
SM5 4NX  
+44 7932857109  
magda.atta.motte@consultant.com

## 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/cm<sup>2</sup> was used for all treatments. This research protocol adheres to patch test treatment settings such as fluence (J/cm<sup>2</sup>) 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/cm<sup>2</sup>) 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-cm<sup>2</sup> 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  
Poland  
31-443

## **Sponsor information**

**Organisation**  
Klinika Młodości

**Sponsor details**  
ul. Lakowa 27  
Krakow  
Poland  
31-443

**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? |
|------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>    | results | 15/03/2020   | 19/02/2021 | Yes            | No              |
| <a href="#">Other publications</a> |         | 25/02/2019   | 30/12/2022 | Yes            | No              |