Low radiant exposures delivered by high-frequency and/or long-pulsed diode laser energy output in hair reduction: an intrapatient comparative, randomized double-blind trial (D800RCS)

First published: 21/03/2015

Last updated: 22/04/2017

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/18713

EU PAS number

EUPAS9050

Study ID

18713

DARWIN EU® study

No

Study countries

Slovenia

Study description

This is a randomized patient- and assessor-blinded study aimed at studying efficacy and safety of various output parameters of diode hair removal lasers. Until now a majority of hair reduction lasers (diode and alexandrite) has been using pulse widths of 3-30 ms though selective photothermolysis theory predicts that pulse durations closer to 100 ms should be safer and more effective. The study is thus aimed at comparing either medium radiant exposure (18-20 J/cm2) longer pulses (100 ms) or low radiant exposure (6 J/cm2) but high frequency (10 Hz) pulses with multiple passes (up to 10) to a standard diode laser approach (25-35 J/cm2, 12.5-30 ms, single pulsed) in hair reduction. Both safety and efficacy will be looked at up to one year after completion of six laser treatments in the paired axiallar and bikini areas.

Study status

Planned

Research institutions and networks

Institutions

Parmova Dermatology Center

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Institution

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/03/2015

Actual: 23/03/2015

Study start date

Planned: 09/05/2015

Date of final study report

Planned: 24/05/2017

Sources of funding

- Other

More details on funding

Own funds

Study protocol

CT protocol diode laser hair removal DCP.pdf(137.9 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Clinical trial

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To show that the use of a low radiant exposure (6 J/cm2), standard pulse width (30 ms) and high repetition frequency (10 Hz) or the use of a medium radiant exposure (18 J/cm2), longer pulse width (100 ms) and medium repetition frequency (4 Hz) diode laser is equally efficacious but safer than standard diode laser hair reduction protocol (25-35 J/cm2, 12.5-30 ms, 1 Hz).

Study Design

Clinical trial randomisation

Randomised clinical trial

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

30

Study design details

Outcomes

The primary outcome parameter is reduction of hair growth evaluated 3 and 6 months following the last treatment. Secondary outcome parameters are treatment-related pain, adverse effects and treatment duration, as well as patient-rated efficacy evaluated 3 and 6 months following the last treatment.

Data analysis plan

Primary outcome analysis is based on the reduction of hair growth at the follow-up visits in the intention-to-treat (ITT) population. ITT was defined as all patients who had received all 6 study treatments. Missing values at visit 8 were implemented using the conservative last-observation-carried-forward (LOCF) approach. Additionally, a per-protocol (PP) analysis was performed as a sensitivity analysis. The goal of the trial is to show non-inferiority of the new treatment protocols.All data were analysed with the paired two-sample Student’s t-test because the baseline data were normally distributed. All data are given as mean ± SD. A P-value below 0.05 was considered significant. To assess consistency in hair counts, a Mann–Whitney U-test was performed. The patient satisfaction were compared between two lasers by using Wilcoxon Signed-Rank test. The differences of treatment time and p

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No