Efficacy test of a laser treatment device for skin rejuvenation

Published: 08-11-2011
Last updated: 28-04-2024

The primary objective is to achieve clinical relevance of the efficacy for the purpose of wrinkle and/or fine line reduction on periorbital area. In addition, to evaluate whether sensation and side effects experienced, e.g. sensation, down-time,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37360

Source
ToetsingOnline

Brief title
Efficacy test for skin rejuvenation

Condition

- Other condition

Synonym
fine lines, wrinkles

Health condition

skin aging

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: fine line, fractional laser, periorbital area, wrinkles

Outcome measures

Primary outcome

Objective assessment of wrinkle grade before and after treatment

Objective assessment of improvement of wrinkle and/or fine line.

Secondary outcome

Subjective evaluation of improvement of wrinkle and/or fine line;

Perceived sensations in the course of treatment.

Study description

Background summary

Laser Induced Optical Breakdown (LIOB) is a novel Philips proprietary technology for skin rejuvenation that creates microscopic isolated damage areas within tissue below epidermis level. This leads to a natural healing response and consequently skin remodelling, resulting in skin rejuvenation effects. The benefit of this technique is that it is a safe procedure potentially without serious side effects and with high efficacy. In 2009, the effectiveness of the prototype has been confirmed in both ex-vivo and in-vivo skin treatments (the study with WMO registration number of M0-1953 titled *Skin response assessment of a laser treatment device for skin rejuvenation). The efficacy of wrinkle and fine line reduction has been proved in the pilot efficacy study in 2010 with WMO registration number of M10-1011 titled *In-vivo pilot efficacy test of a laser treatment device for skin rejuvenation*. In these in-vivo studies, it reveals that skin has been microscopically damaged in dermal layer by laser treatment and skin top layers, i.e. stratum corneum and epidermal layer, are remained unaffected as expected indicating the treatment is rather safe. After the treatment, new collagen formation was found from the histology work, and reduction of wrinkles and fine lines was confirmed subjectively and

objectively. Additionally, the treatment was very acceptable by all test subjects by scoring the pain sensation from *not perceptible* to *perceptible but not painful*.
With this proposed study we want to achieve clinical relevance of the efficacy for wrinkle and/or fine lines reduction on periorbital area, to evaluate whether the sensation and side-effects experienced during skin treatment with the prototype device are well accepted by test subjects

Study objective

The primary objective is to achieve clinical relevance of the efficacy for the purpose of wrinkle and/or fine line reduction on periorbital area. In addition, to evaluate whether sensation and side effects experienced, e.g. sensation, down-time, post-treatment effects etc, are accepted by test subjects.

Study design

This study is a randomized, split-face, non-blinded study.

Study burden and risks

Each subject will experience maximum 8 treatment sessions at the test site. During the treatment session, the periorbital area with appearance of wrinkle on one side of the face will be treated by the test researchers. Each treatment session will take approximately 75 minutes. During the treatment session, the subjects will be asked about their sensations. Subjects will likely experience erythema and/or slight edema after treatment, which are defined as study endpoints, and these, if any, will all be transient.
Risk for adverse skin responses, e.g. blistering, pigmentary changes, scarring, is very low.
The benefit of this study is the potential improvement of wrinkle and/or fine lines.

Contacts

Public
Philips Research

Professor Holstlaan 4, Philips Research, High Tech Campus 34, Postbox 7.071
5656AE, Eindhoven
NL
Scientific
Philips Research

Professor Holstlaan 4, Philips Research, High Tech Campus 34, Postbox 7.071
5656AE, Eindhoven
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy with wrinkle and/or fine lines in periorbital area

Exclusion criteria

see extensive exclusion criteria on page 30-31 in the protocol

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2011
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL37801.060.11