Fractional laser as treatment option for various pigment disorders

Published: 06-02-2009
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The primary objective of this study is to assess the efficacy and safety of non ablative and ablative fractional lasers in various pigment disorders.

Ethical review	Approved WMO
Status	Pending
Health condition type	Pigmentation disorders
Study type	Interventional

Summary

ID

NL-OMON33568

Source
ToetsingOnline

Brief title
Fractionallaserinpigmentdisorders

Condition

- Pigmentation disorders

Synonym
pigment disorders, spotted disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fractional laser, Pigment disorders

Outcome measures

Primary outcome

Objective colour measurements by physician*s global assessment (PhGA), reflectance spectroscopy, clinical melasma score (MASI), patient*s satisfaction, patient*s global assessment (PGA), and visual assessment of side effects.

Secondary outcome

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Study description

Background summary

Local bleaching is the first choice for the treatment of melasma, postinflammatory hyperpigmentation, Q-switched ruby laser is the first choice for the treatment of Resistant Ota naevus. However, the outcome is highly variable and there is a substantial part of patients with a poor result. No treatment options are available for Becker naevus, ochronosis, and ashy dermatosis. Recently non ablative fractional laser (such as the Starlux 1540 nm laser (PALOMAR) or FRAXEL RE:STORE 1550 nm laser (RELIANT)) and ablative fractional laser (such as LUMINUS encore fractional CO2 laser (LUMINUS) or FRAXEL RE:PAIR laser (RELIANT)) were suggested to be effective in the treatment of hyperpigmented disorders.
According to our previous experience the non ablative fractional laser appeared to be a safe and effective treatment option as compared to local bleaching (triple therapy) in 22 patients with moderate to severe melasma (publication in preparation).

Study objective

The primary objective of this study is to assess the efficacy and safety of non ablative and ablative fractional lasers in various pigment disorders.

Study design

Prospective single blinded randomised controlled split-lesion trial

Intervention

fractional laser therapy every 3-6 weeks with a maximum of 5 treatments dependant on skin type and disorder

Study burden and risks

Subjects participating in the study will be asked to visit the SNIP 3-7 times depending on disorder and skin type. The time investment will be 40 minutes for visits with a laser treatment and 20 minutes for all follow up visits. No invasive procedures will be performed. The objective colour measurement involves a handheld device producing a harmless flash of light. The laser procedure is moderately painful which makes the local application of lidocain cream 2 hours before treatment necessary. Known side effects of the laser procedure are local stinging, burning and erythema for several hours or days. Side effects of our standard topical bleaching, the triple therapy, may be perioral dermatitis, exacerbation of acne, telangiectasia, local irritation and hyperpigmentation.
All together the burden due to the study is moderate and the risk for local side effects is low. Systemic side effects are not associated with any of the involved treatments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Melasma and postinflammatory hyperpigmentation : skin photo type I-V ;
Becker naevus: skin photo type I-III ;
Ochronosis and ashy dermatosis : skin photo type IV-V ;
resistant Ota naevus: skin photo type III-IV ;
Subjects attending the outpatient department of the Netherlands Institute for Pigment Disorders;
Age at least 18 years;
Subject is willing and able to give written informed consent.

Exclusion criteria

Bleaching cream during the past 6 weeks;
Local corticosteroids during the past 6 weeks;
Subjects with a history of keloid;
Subjects with active eczema;
Subjects with active acne in the face;
Subjects with a history of facial eczema;
Suspect allergy to lidocaine or triple therapy;
Use of roaccutane in the past 6 months;
Subjects not competent to understand what is involved;
Pregnancy;
Lesion suspicious for malignancy;
High exposure to sunlight (vacation in southern countries) or UV light (UVA or UVB).

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL26170.018.08