Ablative 10600 nm fractional laser for the treatment of scars

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The primary objective of this study is to assess the efficacy and safety of 10600 nm fractional laser therapy for the treatment of different types of scars.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35000

Source
ToetsingOnline

Brief title
Fractional laser in scars

Condition

- Other condition
- Epidermal and dermal conditions

Synonym
cicatrix, scar

Health condition

littekens

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, laser, scar, therapy

Outcome measures

Primary outcome

Blinded Physicians Global Assessment is the main outcome variable.

Secondary outcome

Secondary variables are Patient*s Global Assessment, blinded clinical

assessment of the scar on a scale from 0-3 (erythema, pigmentation, texture,

hypertrophy, atrophy, pliability), Patient and Observer Scar Scale (POSAS),

objective colour measurements by reflectance spectroscopy (LAB) and chromameter

(erythema index, melanin index).

Study description

Background summary

Scars can be highly disfiguring and may result in functional impairment and psychosocial problems. Recently, fractional laser therapy (FLT) has been introduced as a promising novel treatment modality for both atrophic and hypertrophic scars.

Study objective

The primary objective of this study is to assess the efficacy and safety of 10600 nm fractional laser therapy for the treatment of different types of scars.

Study design

Prospective observer blinded randomized controlled split-lesion trial.

Intervention

A test region (at least 2x2cm but smaller than 5x5cm) will be treated three times every four weeks with the UltraPulse Encore 10600nm Deep FX fractional laser. First, the skin will be cleaned with chlorhexidin solution. Next, the test region allocated to laser treatment will be locally anaesthetised by infiltration with lidocaine 2%/epinephrine 1:80000. Post treatment care starts directly after each treatment session and involves thrice daily application of fucidic acid cream during 3 days.

Study burden and risks

Subjects participating in the study will be requested to visit the SNIP (Amsterdam) 3 times for treatment and 2 times for follow-up. The time investment per visit will be 30 minutes for treatment sessions and 20 minutes for follow-up visits. Fractional laser therapy using a 10600 nm laser device is a procedure with FDA approval for both the device (UltraPulse Encore 10600 nm) and the indication (scar). Local side effects are erythema (always; 1-2 weeks), oozing (often; 1-3 days), swelling (always, 1-4 days), blisters < 0.5cm (occasionally) and blisters > 0.5cm (very rare). No systemic side effects are known for this laser device.
The burden due to the study is moderate, side effects are generally local and mild. Systemic side effects are not reported with this treatment. There is an indirect benefit for the participating subject. In case of improvement of the treated test regions, this therapy can be directly utilized to treat the whole scar.

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

Atrophic or hypertrophic scars allowing for demarcation of two similar test regions of at least 2x2 cm;
Age at least 18 years;
Subject is willing and able to give written informed consent;
Interval between injury and start of study at least one year.

Exclusion criteria

Suspected allergy to lidocaine;
Use of isotretinoin in the past 6 months;
Subjects not competent to understand what is involved;
Skin type V and VI
Pregnancy;
Concomitant skin disease at the site of treatment;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2010
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Generic name:	UltraPulse Fractional CO2 laser
Registration:	Yes - CE intended use

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	NL31358.018.10