Fractional Photothermolysis versus triple therapy for the treatment of melasma: a randomised controlled trial

Published: 25-09-2007
Last updated: 08-05-2024

The primary objective of this study is to assess the efficacyand safety of the fraxel laser as compared to a potent bleaching cream (triple therapy) in the treatment of melasma.

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

Summary

ID

NL-OMON31310

Source
ToetsingOnline

Brief title
Fraxel laser in melasma

Condition

- Pigmentation disorders

Synonym
chloasma, mask of pregnancy

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 photothermolysis, laser, melasma

Outcome measures

Primary outcome

Objective colour measurements by reflectance spectroscopy before and after

therapy

Clinical melasma score (MASI score) before and after therapy

Secondary outcome

Quality of life

Patient's satisfaction

Study description

Background summary

Local bleaching is the first choice for the treatment of melasma. However, the outcome is highly variable and there is a substantial part of patients with a poor result of the bleaching treatment. The triple therapy is the first choice for the treatment of melasma. Especially patients with dermal melasma are known to be resistant to any kind of local treatment. Recently fractional photothermolysis was suggested to be effective in the treatment of melasma.

Study objective

The primary objective of this study is to assess the efficacy
and safety of the fraxel laser as compared to a potent bleaching cream (triple therapy) in the treatment of melasma.

Study design

Prospective randomised controlled single blinded parallel group pilot study

Intervention

Triple therapy
Triple therapy will be applied once daily for 8 weeks. The triple therapy combines a moderately potent corticosteroid (triamcinolon acetonide 0.1%), retinoic acid 0.05% and hydrochinon 5% in cremor lanette II. This cream is applied once a day in the evening on all hyperpigmented macules.
Fraxel laser
One hour before laser treatment patients will apply a topical anaesthetic cream (EMLA cream). Then the skin will be washed with cleanser. Then the skin will be prepared with 70% alcohol. One treatment consists of eight passes with the device to create a final treatment density of 2000 microthermal treatment zones (MTZ) per cm2. Four passes are made in one direction and four passes are made in a perpendicular direction. The average fluence (radiant exposure) per pass is 2-3 J/cm2, and total treatment fluence (radiant exposure) will be 20 J/cm^2. Subsequent laser treatments are provided at 2 week intervals, and all subjects will receive a total of 4 laser treatments.

All subjects will be advised to use topical sun protection (SPF>50).

Study burden and risks

The risk for irreversible side effects is very low for both intervention. The triple therapy is the first choice of treatment worlwide. It is used routinely since more than 10 years at our institute. We sometimes see mild local skin irritation which disappears spontaneously after stopping the medication.
The fractional photothermolysis used in the present study is the Fraxel laser which has FDA approval for the treatment of melasma. the laser treatment is moderately painful. Both treatment can lead to erythema, burning sensation, vesicles, hyperpigmentation or hypopigmentation. Often we see swelling of the treated skin directly after laser treatment. Scras have not been reported by any of the two treatments.
Participants need to visit our institute regularly for treatment and follow-up visits. There are no invasive procedures.

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

- patiënts with moderate to severe melasma
- skin photo type II-V
- subjects attending the outpatient department of the Netherlands Institute for Pigment Disorders
- age at least 18 years

Exclusion criteria

- bleaching cream or local corticosteroids during the past 4 weeks
- subjects with a history of keloid
- subjects with a history of facial eczema
- allergy to lidocaine
- use of roaccutane in the past 6 month

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-10-2007
Enrollment:	20
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
Other	CCT-NAPN-16718
CCMO	NL18605.018.07