Fractional laser abrasion in combination with UVB therapy in vitiligo patients: a randomized controlled study

Published: 18-07-2014
Last updated: 24-04-2024

To assess the efficacy and patient safety of (1)fractional laser treatment in combination with NB- UVB,(2) fractional laser treatment in combination with NB- UVB and topical corticosteroids versus NB-UVB treatment alone.

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

Summary

ID

NL-OMON40502

Source
ToetsingOnline

Brief title
Fractional laser in combination with UVB therapy in vitiligo patients

Condition

- Pigmentation disorders

Synonym
leukoderma

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, UVB, vitiligo

Outcome measures

Primary outcome

Main study parameter/endpoint:

Objective assessment of the degree of repigmentation 6 months after the first fractional laser therapy. Assessment will be done on sheets, using a digital image analysis system. Software based on Matlab will be used to analyse the images and to calculate the depigmented surface. By comparing pre- and post treatment images, the surface showing repigmentation can be computed.

Secondary outcome

Secondary study parameters/endpoints:

- Visual assessment of side effects per treatment region (hyperpigmentation, hypo- pigmentation and scar formation on a scale from 0-3) will be done by a blinded investigator.

- General outcome will be assessed by the patient and physician per treatment region on a scale from 0-3

- Colour difference i.e. the difference between erythema and pigmentation will be assessed with a Derma-spectrometer

Study description

Background summary

Vitiligo is a common skin disorder that can impair a patient*s quality of life. Many depigmented lesions in vitiligo patients remain therapy resistant for medical treatment. Therefore new therapeutic options in these patients are necessary. Currently, dermabrasion by conventional or fractional laser therapy in combination with NB-UVB therapy and steroids appears to be effective in therapy resistant areas. However, little literature on this combination is available.

Study objective

To assess the efficacy and patient safety of (1)fractional laser treatment in combination with NB- UVB,(2) fractional laser treatment in combination with NB-UVB and topical corticosteroids versus NB-UVB treatment alone.

Study design

Prospective observer blinded randomised intra-patient controlled study.

Intervention

Three NB-UVB resistant depigmented regions on the trunk or extremities will be randomly allocated to;(1) NB-UVB treatment in combination with fractional CO2 laser abrasion, or (2)NB-UVB treatment in combination with fractional CO2 laser abrasion and topical steroids, or (3)NB-UVB treatment alone. NB-UVB treatment and topical steroids will be given according to the standard treatment protocol of the SNIP and continued for at least 6 months and 6 months after the first laser treatment, the percentage of repigmentation of the lesions will be assessed.

Study burden and risks

Patients will not miss any regular treatment. The study involves depigmented lesions which are therapy resistant to current NB-UVB treatment. The time investment for the patient will be approximately 75 minutes for the intake including the first laser treatment and half an hour for the follow up visits. Side effects: infection in the treated area may occur but is rare and the risk of scarring is very low. Although erythema of the laser-treated areas does occur often, this is generally temporary. In case of improvement of the depigmentation, the most efficacious treatment modality will be offered to treat the whole depigmented skin area.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients with non segmental (generalised) vitiligo visiting the Netherlands Institute for Pigment Disorders
- receiving NB- UVB treatment for 3 to 6 months
- Age >18 years
- At least 3 therapy resistant vitiligo lesions on the extremities or trunk larger than 5x5 cm or one vitiligo lesion on the extremities or trunk of at least 5x15 cm.
- Patient is willing and able to give written informed consent

Exclusion criteria

- Skin type I
- Recurrent HSV skin infections
- Hypertrophic scars
- Keloid
- Cardial insufficiency

- Patients who are pregnant or breast-feeding
- Patients not competent to understand what the procedures involved
- Patients with a personal history of melanoma or non-melanoma skin cancer
- Patients with atypical nevi.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	fractional CO2 laser treatment
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	18-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	11-02-2015
Application type:	Amendment
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	NL45970.018.13