Effect of fluticasone proprionate 0.05% cream on narrow band UV-B phototherapy in active vitiligo: a randomised single blinded controlled trial

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The objective of this study is to evaluate the difference in clinical effects (onset and degree of repigmentation) of NB-UVB and fluticasone proprionate vs NB-UVB alone.

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

Summary

ID

NL-OMON33795

Source
ToetsingOnline

Brief title
UVBVIT

Condition

- Pigmentation disorders

Synonym
vitiligo, white spot 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: fluticasone proprionate, narrow band UVB phototherapy, vitiligo

Outcome measures

Primary outcome

The onset and degree of pigment spread is assessed by digital image analysis,

and the patients and doctors satisfaction will be evaluated

Secondary outcome

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Study description

Background summary

Vitiligo is a common idiopathic acquired pigment disorder, which is characterised by spreading depigmented macules, often with a progressive course. Several treatment options are available; non-surgical therapies and surgical therapies. Non-surgical therapies include topical treatment (fluticasone proprionate or tacrolimus) and phototherapy (narrow band Ultra Violet B (NB-UVB)). Fluticasone proprionate is applied once a day the first 3 months, month 3-12, 3 times a week (pulse scheme) on affected areas and suppresses the depigmenting process. Exposure to NB-UVB twice a week stimulates the spreading of melanocytes.
To our knowledge to date there are no publications comparing NB-UVB and topical treatment of fluticasone proprionate to NB-UVB alone.

Study objective

The objective of this study is to evaluate the difference in clinical effects (onset and degree of repigmentation) of NB-UVB and fluticasone proprionate vs NB-UVB alone.

Study design

Prospective single blinded randomised controlled study

Intervention

NB UVB phototherapy twice a week for twelve months with either topical use of fluticasone proprionate or NB UVB phototherapy alone

Study burden and risks

Subjects participating in the study will be asked to visit the SNIP 6 times. The time investment will be 15 minutes per visit. No invasive procedures will be performed. Known side effects of the NB-UVB phototherapy are redness, pruritus, xerosis cutis, burning sensation and conjunctivitis. All together the burden due to the study is low and the risk for local side effects is low. Systemic side effects (suppression of the adrenocortex) are associated with the involved treatment (fluticasone proprionate 0.05% cream 0.05%), however because a maximum of 30% body area is treated (i), and the regions which are known to have a higher absorption are excluded (periorbital, axillary, inguinal and genital area) (ii), this side effect is not expected.

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

Patients with active vitiligo, eligible for NB-UVB phototherapy;
Subjects attending the outpatient department of the SNIP;
Adult patients: * 18 years;
Subject is willing and able to give written informed consent.

Exclusion criteria

With a personal or a family history of skin cancer (non-melanoma skin cancer: first degree family members, melanoma: any family member)
With a personal history of photosensitivity and/or phototoxicity disorders
With skin type I (according to Fitzpatrick classification I-VI)
Who are pregnant
Who are taking medications known to cause photosensitivity and/or phototoxicity and chronic or very frequent use of any medication that can influence the UVB response (eg. tetracycline, retinoids, sulfonamids, psoralens, NSAID*s)
With other skin diseases that would impair evaluation of repigmentation, such as psoriasis and eczema.
Who are not able to have 2 times weekly NB-UVB phototherapy
With local immunosuppressive treatment or 6 weeks prior to enrolment. For these patients a washout period of 6 weeks will be required.

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):	01-01-2009
Enrollment:	70
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	cutivate
Generic name:	fluticasone proprionate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	12-11-2008
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
EudraCT	EUCTR2008-006903-22-NL

Register	ID
Other	NA
CCMO	NL25499.018.08