NB-UVB phototherapy versus excimer laser after minigrafting in vitiligo patients.

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308-nm Excimer lasertherapy will obtain faster repigmentation after minigrafting than NB-UVB therapy in vitiligo patients.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29475

Bron
NTR

Verkorte titel
NB-UVB vs Excimer

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage, start and grade of repigmentation.

Toelichting onderzoek

Achtergrond van het onderzoek

Vitiligo is a common, idiopathic acquired pigment disorder. Several treatment options are available; non-surgical therapies and surgical therapies. Surgical therapies can be considered for stable vitiligo patches. In the Netherlands Institute for Pigment Disorders (NIPD) we routinely use the autologous minigrafting technique. This technique is relatively simple among the surgical modalities and has been an effective therapy for stable localised and generalised vitiligo. Exposure to Narrow-Band Ultraviolet B (NB-UVB)following the minigrafting stimulates the spreading of melanocytes from the treated vitiligo lesion and obtains a faster rate of repigmentation. Recently the 308-nm Excimerlaser is introduced as an effective method of treatment for vitiligo and appears to be more effective than NBUVB as it produces more rapid and profound repigmentation.

To our knowledge, no studies have been published on minigrafting followed by NB-UVB versus Excimer laser.

The aim of this study is to evaluate the clinical effects (start and grade of repigmentation) of NB-UVB versus 308-nm Excimer lasertherapy on pigment spread after minigrafting in vitiligo patients.

Doel van het onderzoek

308-nm Excimer lasertherapy will obtain faster repigmentation after minigrafting than NB-UVB therapy in vitiligo patients.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Minigrafting in two symmetrical vitiligo patches on the trunk or extremties.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Consecutive patients, diagnosed with stable vitiligo vulgaris* with symmetrical vitiligo patches.

*Vitiligo vulgaris: a few to many widespread depigmented macules over the entire body, with often a symmetrically distribution pattern.

Stable means: no expansion of existing lesions or appearance of new lesions during the previous 6 months, absence of Koebner's phenomenon and a positive minigrafting test;

2. Patients, eligible for minigrafting and NB-UVB/excimer therapy;

3. Adult patients: older than 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients:

1. With a history of hypertrophic scarring and/or keloid;

2. History of allergic/phototoxic reaction (Lidocaine, Tegaderm, Suture strips, sunlight);

3. With a negative minigrafting test;

4. With a personal or a family history of skin cancer (non-melanoma skin cancer: first degree family members, melanoma: any family member);

5. With a personal history of photosensitivity and/or phototoxicity disorders;

6. With skin type I (according to Fitzpatrick classification I-VI);

7. Who are pregnant;

8. 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);

9. With other skin diseases that would impair evaluation of repigmentation, such as psoriasis and eczema;

10. Who are not able to have 2 times weekly NB-UVB/Excimer therapy;

11. With local immunosuppressive treatment or 6 weeks prior to enrolment. For these patients a washout period of 6 weekswill be required.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving gestopt

(Verwachte) startdatum:	01-09-2006
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	03-10-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL778
NTR-old	NTR789
Ander register	: N/A
ISRCTN	ISRCTN68425813

Resultaten

Samenvatting resultaten
N/A