

NB-UVB phototherapy versus Excimer laser after mini-grafting in vitiligo patients

Submission date 16/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/01/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/01/2021	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL778, NTR789

Study information

Scientific Title
NB-UVB phototherapy versus Excimer laser after mini-grafting in vitiligo patients

Acronym

NB-UVB vs Excimer

Study objectives

308-nm Excimer laser therapy will obtain faster repigmentation after mini-grafting than Narrow Band UltraViolet B (NB-UVB) therapy in vitiligo patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical ETHics Committee of the Academic Medical Centre in Amsterdam (Medisch Ethische Commissie) on the 23rd August 2006.

Primary study design

Interventional

Study design

Randomised, controlled, crossover, single blinded trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Vitiligo

Interventions

Mini-grafting in two symmetrical vitiligo patches on the trunk or extremities.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Percentage, start and grade of repigmentation.

Key secondary outcome(s)

Patient satisfaction.

Completion date

01/09/2007

Eligibility**Key inclusion criteria**

1. Consecutive patients, diagnosed with stable vitiligo vulgaris (a few to many widespread depigmented macules over the entire body, with often a symmetrically distribution pattern) with symmetrical vitiligo patches. Definition of stable: no expansion of existing lesions or

appearance of new lesions during the previous six months, absence of Koebner's phenomenon and a positive mini-grafting test

2. Patients, eligible for mini-grafting and NB-UVB/excimer therapy

3. Adult patients: older than 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

14

Key exclusion criteria

Patients:

1. With a history of hypertrophic scarring and/or keloid
2. With a history of allergic/phototoxic reaction (Lidocaine, Tegaderm, Suture strips, sunlight)
3. With a negative mini-grafting 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 (e.g. tetracycline, retinoids, sulfonamids, psoralens, Non-Steroidal Anti-Inflammatory Drugs [NSAIDs])
9. With other skin diseases that would impair evaluation of repigmentation, such as psoriasis and eczema
10. Who are not able to have two times weekly NB-UVB/Excimer therapy
11. With local immunosuppressive treatment six weeks prior to enrolment. For these patients a washout period of six weeks will be required

Date of first enrolment

01/09/2006

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

ROR
<https://ror.org/03t4gr691>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Center (AMC) (The Netherlands)

Alternative Name(s)
Academic Medical Center, Centre Médical Académique, ACADEMISCH MEDISCH CENTRUM AMSTERDAM, Academic Medical Center (Amsterdam), AMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2012	15/01/2021	Yes	No