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

Submission date	Recruitment status
16/01/2007	No longer recruiting
Registration date	**Overall study status**
16/01/2007	Completed
Last Edited	**Condition category**
15/01/2021	Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Randomised, controlled, crossover, single blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Vitiligo

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

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Percentage, start and grade of repigmentation.

Secondary outcome measures
Patient satisfaction.

Overall study start date
01/09/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
24

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)

Sponsor details
Department of Dermatology
Netherlands Institute of Pigmentary Disorders
Meibergdreef 35
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

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, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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