Autologous cell suspension grafting using ReCell in vitiligo and piebaldism patients: a randomized controlled pilot study

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The purpose of the present randomized controlled pilot study is to assess the efficacy, safety and practical aspects of autologous epidermal cell suspension grafting using ReCell in segmental vitiligo and piebaldism patients. Results of this study...

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

Summary

ID

NL-OMON37399

Source
ToetsingOnline

Brief title
Autologous cell suspension grafting using ReCell

Condition

- Pigmentation disorders

Synonym
leucoderma

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Nederlands Instituut voor Pigmentstoornissen

Source(s) of monetary or material Support: Ministerie van OC&W,Avita Medical

Intervention

Keyword: cell suspension grafting, piebaldism, ReCell, vitiligo

Outcome measures

Primary outcome

Main study parameter/endpoint:

* Objective assessment of the degree of repigmentation 6 months after autologous epidermal cell suspension grafting. Assessment will be done by standardized (UVA) photographs and a digital image analysis system. A Canon G6 is used under standardized circumstances (camera setting, distance and UVA flash) to obtain digital images before and after treatment. 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.

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

* General outcome will be assessed by the patient per treatment region on a scale from 0-3 (Poor, Moderate, Good, and Excellent).

Secondary outcome

* The superfluous of the suspension will be used for cellular analyses, to investigate the density of viable melanocytes, keratinocytes, stemcells, viable melanocytes and keratinocytes in the cell suspension.

* Adverse events of the procedure will be documented

Study description

Background summary

Vitiligo and piebaldism are cutaneous conditions associated with white patches in patients. These depigmented lesions can be acquired (vitiligo) or congenital (piebaldism). Vitiligo and piebaldism can alter a patients* appearance dramatically and impair the patients* quality of life. In stable unresponsive depigmented lesions autologous melanocyte transplantation is the treatment option of choice. Various methods of autologous melanocyte transplantation have been developed to treat stable unresponsive depigmented lesion. The basic principle of all these surgical techniques is to transplant (autologous) melanocytes from the normal pigmented skin to the depigmented macules where melanocytes are absent.
Current treatment recommendations for choosing a transplantation method are based on data from a limited number of studies, and on personal experience and technical possibilities. Until recently, it was technically not possible to treat patients with autologous epidermal cell suspension grafting in the NIPD. Therefore, we routinely use the autologous punchgrafting technique as surgical therapy. Punchgrafting shows good (more than 70 %) repigmentation in 68- 82 % of the patients treated, although this technique is not suited for large lesions. Long term follow-up studies on autologous cell suspension grafting, suggest that it is an effective and safe method.19 Results of 52 treated locations indicated a repigmentation rate of 95 % - 100% in segmental and piebaldism patients and a rate of 49% in vitiligo vulgaris patients. One study on five lesions that compared conventional melanocyte-keratinocyte transplantation with ReCell concluded that there was no difference in the efficacy and safety of both methods. ReCell showed to be a simple, safe and effective method, although further research is required.
To date, only small series are published on the efficacy of ReCell in vitiligo. A randomized controlled trial is not available yet.

Study objective

The purpose of the present randomized controlled pilot study is to assess the efficacy, safety and practical aspects of autologous epidermal cell suspension grafting using ReCell in segmental vitiligo and piebaldism patients. Results of this study may have an impact on our future practice in the treatment of vitiligo and piebaldism.

Study design

The study will be a prospective single (observer) blinded randomized controlled pilot study conducted at the Netherlands Institute for Pigment Disorders (NIPD), Department of Dermatology, Academic Medical Centre, University of Amsterdam, the Netherlands.
In each patient three (parts of) depigmented lesion(s) are randomly allocated to receive one of the following regimes:

1) CO2 laser abrasion + ReCell epidermal skin graft suspension + UV-therapy
2) CO2 laser abrasion + UV-therapy
3) No treatment + UV-therapy

Intervention

In each patient three (parts of) depigmented lesion(s) are randomly allocated to receive one of the following regimes:

1) CO2 laser abrasion + ReCell epidermal skin graft suspension + UV-therapy
2) CO2 laser abrasion + UV-therapy
3) No treatment + UV-therapy

The donor site will be the hip region. Before treatment, the donor site will be injected with a local anaesthetic: Lidocain 2 % . A split-thickness skin biopsy of approximately 2x2 cm in area will be harvested at a depth of 0.15 to 0.2mm with a dermatome. The skin biopsy that is obtained will be placed in the heated enzyme solution in the device for a period of 15-20 minutes to allow cell disaggregation. After 15-minutes, the skin biopsy will be removed from the enzyme solution and a check takes place if scraping could be performed. If not, the skin biopsy will be returned to the enzyme solution for a further 5-10 minutes before being tested again. When the test scrape is successful, the biopsy will be dipped in the buffer solution to wash off any residual enzyme. The biopsy will be scrapped to disaggregate the cells from the dermal epidermal junction. The epidermal cells are then drawn up in a 5ml syringe and the prepared suspension will be sprayed/ dripped on both the donor and the prepared acceptor site.

Acceptor Site
Before treatment the acceptor site will be injected with a local anaesthetic of Lidocain 2 %. According to current standard of care procedures the treatment site will be superficially abraded using an ablative laser (10,600nm CO2 laser) after which the prepared suspension will be sprayed on.

Control Site preparation
As control sites, 2 similar depigmented lesions will be used. One site will be abraded using the same laser, and the same settings but will not receive an epidermal suspension. The other site wll only receive UV- treatment.

Post-Operative Care

Oral antibiotics will be administered after the procedure .
The donor site, dermabraded control site and acceptor site wounds will be covered with a non-adherent, low-absorbent, small-pore dressing (Telfa Clear* Wound Dressing, Covidien). For recipient sites, a secondary dressing of greasy gauze (e.g. Jelonet*) or saline soaked gauze is placed over the Telfa Clear primary dressing. The Telfa Clear primary dressing should remain in situ for 6-8 days. Secondary dressings can be replaced as needed. At 6-8 days post-treatment, the patient will return to the NIPD for dressing removal. Once the primary dressing has been removed, a dressing according to standard NIPD protocol will be applied to protect the wound surface, with or without an adhesive retention dressing as clinically indicated.

Study burden and risks

Subjects participating in the study will not experience any delay or disadvantage in the medical care of vitiligo as with such large lesions we normally do not perform autologous transplantation. Consequently, patients who participate in this study will not miss any regular treatment. Subjects participating in the study will be requested to visit the NIPD (Amsterdam) once to receive treatment, once for dressing removal and 2 times for evaluation and follow-up.

Local side effects of the ReCell procedure for both donor site and acceptor site are erythema (always 1-2 weeks), pain (often 1 day), itching (1-2 weeks), burning sensation (often 1-3 days), local swelling (often 1-3 days), scar formation (rare), hypo- and or hyper pigmentation (common). Infection in the grafted area may occur but is very rare in our hands. No systemic side effects are known for this treatment.
All outcome measures involve non-invasive procedures. Autologous epidermal cell suspension grafting is a painful procedure that requires effective local anesthesia.
All together the burden due to the study consists of treatment time, which will be 2 hours and additional time investment of 3 visits to the NIPD consisting of 1 hour. Systemic side effects are not associated with any of the involved treatments.
There will be a direct advantage for the patient as the treated area could show repigmentation. In case of improvement of the depigmentation, the most efficacious treatment can be utilized to treat the control sites of the depigmented macule also.
Considering the lack of treatment options in these vitiligo depigmentations, the balance between burden, possible side effects and prospect for improvement is favorable. Results of this study may have an impact on our future practice in the treatment of vitiligo and piebaldism.

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 segmental vitiligo or piebaldism under medical treatment at the Netherlands Institute for Pigment Disorders
Age >18
Patient is willing and able to give written informed consent
Segmental vitiligo stable since 12 months without systemic therapy or 6 months without topical therapy as defined by the absence of new lesions and/or enlargement of existing lesions.
At least three vitiligo lesions on the proximal extremities or trunk larger than 3x3 cm or one vitiligo

Exclusion criteria

UV therapy or systemic immunosuppressive treatment during the last 12 months
Local treatment of vitiligo during the last 12 months
Vitiligo lesions with folliculair or non-folliculair repigmentations
Skin type I and II
Recurrent HSV skin infections
Hypertrophic scars
Keloid
Cardial insufficiency
Patients with a history of hypersensitivity to (UVB or UVA) light and/or allergy to local anesthesia.
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 a first degree relative with melanoma skin cancer
Patients with atypical nevi.

Study design

Design

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):	07-08-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	21-05-2012
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
CCMO	NL39892.018.12