Autologous cell suspension grafting using ReCell in vitiligo and piebaldism patients: a randomized controlled study on the recipient site preparation

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Primary: to assess the efficacy and safety of autologous epidermal cell suspension grafting using the ReCell kit after CO2 laser abrasion with superficial full surface ablation, fractional laser treatment and conventional (deep) full surface CO2...

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

Summary

ID

NL-OMON42082

Source
ToetsingOnline

Brief title
ReCell in vitiligo and piebaldism: recipient site preparation

Condition

- Pigmentation disorders

Synonym
piebaldism, segmental vitiligo

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: autologous cell suspension grafting, fractional laser, piebaldism, vitiligo

Outcome measures

Primary outcome

Objective assessment of the degree of repigmentation six months after autologous epidermal cell suspension grafting with a digital image analysing system.

Secondary outcome

-Blinded physician*s assessment of repigmentation using standardized photographs.

-General patient assessed outcome per treatment region on a scale from 0-3 (poor, moderate, good or excellent).

-Visual assessment of side effects per treatment region (hyperpigmentation, hypopigmentation and scarring on a scale from 0-3) by a blinded investigator.

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

Study description

Background summary

Piebaldism and vitiligo are skin conditions characterized by depigmented macules, which are congenital or occur in the course of life, respectively. The lesions are often regarded disturbing by patients and patients may suffer from social stigmatization. Cel suspension grafting is a well recognized treatment

option for stable lesions. In epidermal cell suspension grafting, a split-thickness graft of normally pigmented skin is processed into a cell suspension, which is subsequently applied on the depigmented macules. Before grafting, the depigmented macules are pretreated with an ablative laser, (partially) removing the epidermis. The advantage of this technique is that relatively large depigmented areas can be treated with relatively little donor material. Epidermal cell suspension grafting is carried out in routine clinical practice in specialized centres elsewhere in Europe. In most epidermal cell suspension grafting techniques, specialized laboratory facilities are required. To date, these techniques could therefore not be used at the Netherlands Institute for Pigment Disorders. More recently, the ReCell technique was developed. In this technique, the cell suspension is prepared using a prefabricated kit, enabling treatment in an outpatient clinic. An earlier pilot study conducted at our institute showed that significant repigmentation could be achieved using this method. However, laser pretreatment has been relatively aggressive, resulting is slower wound healing, more patient reported complaints and a higher risk of e.g. scarring. Much is still unknown regarding to laser pretreatment in cell suspension grafting. Pretreatment with less invasive settings (lower ablation depth or pretreatment with so called fractional settings, where an array of microscopic channels is created in the skin, leaving the surrounding skin intact) may also be effective.

Study objective

Primary: to assess the efficacy and safety of autologous epidermal cell suspension grafting using the ReCell kit after CO2 laser abrasion with superficial full surface ablation, fractional laser treatment and conventional (deep) full surface CO2 laser ablation.

Secondary: to assess the practical aspects and the general outcome by the patient, of autologous epidermal cell suspension grafting technique using the ReCell device after different methods to prepare the recipient site and to assess the cellular properties of the cell suspension by analysing the density of melanocytes, keratinocytes, stem cells, viable melanocytes and keratinocytes in the cell suspension.

Study design

Prospective, observer- blinded, randomised, within subject, controlled study.

Intervention

Four depigmented regions on the trunk or extremities will be randomly allocated to:

I CO2 ActiveFx 200 mJ 60 W density 3 (full surface ablation, depth 209 µm) +

ReCell epidermal skin graft suspension
II CO2 ActiveFx 150 mJ 60 W density 3 (full surface ablation, depth 150 µm) + ReCell epidermal skin graft suspension
III CO2 DeepFx 7.5 mJ/ microbeam 20% (fractional ablation, depth 225 µm, width 120 µm) + ReCell epidermal skin graft suspension
IV untreated control region

After the transplantation, UV-treatment according to the standard treatment protocol of the Netherlands Institute for Pigment Disorders will be started on all sites and continued for three months. Six months after grafting, the percentage of repigmentation of the lesions will be assessed.

Study burden and risks

As the study involves large depigmented lesions, which are too large to treat in regular surgical treatment, patients will not miss any regular treatment. The time investment for the patient will be approximately 75 for the treatment session (one hour for the actual grafting procedure), two follow-up visits and 15 minutes twice a week at home for the UV- therapy. Infection in the grafted area or the donor site may occur but is very rare; the risk of scarring in the donor site is moderate. Hyperpigmentation of the treated area does occur often, although this improves over time in most cases. In case of improvement of the depigmentation, the most efficacious treatment modality will be offered to treat the whole depigmented skin area.

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 12 months without topical therapy as defined by the absence of new lesions and/or enlargement of existing lesions.
At least four depigmented lesions on the proximal extremities or trunk larger than 3x3 cm or one depigmented lesion on the proximal extremities or trunk of at least 12x3 cm

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 follicular or non-follicular repigmentations
Skin type I
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 anaesthesia.
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 atypical nevi
Known allergy to clarithromycin

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):	13-05-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	CO2 laser
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-03-2015
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	NL49720.018.14