

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

Published: 13-03-2015

Last updated: 21-04-2024

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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Pigmentation disorders
<b>Study type</b>	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. Cell 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 in 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 CO<sub>2</sub> laser abrasion with superficial full surface ablation, fractional laser treatment and conventional (deep) full surface CO<sub>2</sub> 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 CO<sub>2</sub> 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**

### **Public**

Academisch Medisch Centrum

Meibergdreef 9

Amsterdam 1100 DD

NL

### **Scientific**

Academisch Medisch Centrum

Meibergdreef 9

Amsterdam 1100 DD

NL

## **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

CCMO

### ID

NL49720.018.14