Autologous cell suspension grafting using ReNovaCell in non-segmental vitiligo patients: a randomized controlled study

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Primary: to assess the efficacy and safety of RenovaCell grafting combined with 311 nm UVB therapy and topical anti-inflammatory therapy for the treatment of stable non-segmental vitiligo. Secondary: to assess, satisfaction, cosmetic acceptability,...

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

Summary

ID

NL-OMON46274

Source
ToetsingOnline

Brief title
ReNovaCell in non-segmental vitiligo

Condition

- Pigmentation disorders

Synonym
non-segmental vitiligo, 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, United Kingdom,Avita Medical;United Kingdom

Intervention

Keyword: autologous cell suspension grafting, non-segmental, ReNovaCell, vitiligo

Outcome measures

Primary outcome

Objective assessment of the degree of repigmentation three and six months after RenovaCell grafting with a digital image analysis system. To assess the pigmentation, the contours of pigmentation are copied on a transparent sheet before, three and six months after treatment, after which the sheets are scanned. By comparing pre- and post-treatment pictures, the relative surface showing repigmentation expressed as percentage of the selected treated patch is computed.

Secondary outcome

Secondary outcomes:

- Patient Reported Outcomes: satisfaction, cosmetic acceptability, noticeability

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

- Visual assessment of percentage repigmentation by blinded observer

- 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 and residual lesional punchgrafts will be used for flow cytometric analyses of the cellular composition of the grafted cell suspension, and expression analysis of melanin synthesis-related genes.

These data will be correlated to the clinical data.

Study description

Background summary

Autologous epidermal cell suspension grafting is an effective method of surgical treatment in vitiligo, which is suitable for treating large areas with good cosmetic results. The RenovaCell Autologous Cell Harvesting Device (Avita Medical Europe Limited, Cambridge, UK) (previous name: ReCell) is a device which, compared to other forms of autologous epidermal cell suspension grafting, is easier in use showing similar results. Efficacy and safety of the ReCell device was proven in segmental vitiligo and piebaldism. However, the efficacy in non-segmental vitiligo is not yet confirmed in randomized controlled trials. We hypothesize that grafting using the RenovaCell device in combination with standard of care is also effective in stable non-segmental vitiligo and more effective than standard of care alone.

Study objective

Primary: to assess the efficacy and safety of RenovaCell grafting combined with 311 nm UVB therapy and topical anti-inflammatory therapy for the treatment of stable non-segmental vitiligo.
Secondary: to assess, satisfaction, cosmetic acceptability, noticeability and persistence of repigmentation after RenovaCell transplantation.

Study design

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

Intervention

In patients already receiving standard of care (311 nm UVB therapy + topical anti-inflammatory therapy) 2 comparable depigmented regions are randomised to receive RenovaCell grafting or no grafting. Standard of care will be given according to the standard treatment protocol of our institute.

Study burden and risks

As the study involves large depigmented lesions, which are too large to treat in regular surgical treatment (punch grafting), patients will not miss any regular treatment. The time investment for the patient will be approximately 20 minutes for the punchgrafting session, 75 minutes for the cell suspension

grafting session and 15 minutes for the three follow-up visits. Two of the five visits are part of the standard of care UVB follow-up regimen and are therefore not additional due to the study. Infection in the grafted area or the donor site may occur but is very rare; the risk of mild textural changes 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, patients may receive another treatment for the (contralateral) untreated side.

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, non-segmental vitiligo receiving 6 months of standard of care, consisting of topical corticosteroids or immune modulators and NB-UVB phototherapy

• Age >=18
• Patient is willing and able to give written informed consent
• At least two comparable (in location and diameter) depigmented lesions of at least 10 cm2 or one large lesion of at least 30 cm2 on the extremities, face or trunk - excluding fingers, elbows, feet and knees.

Exclusion criteria

- Patients with signs of activity (spreading of lesions and/or koebnerisation) during standard of care treatment or showing depigmentation in the test punch grafting
- Skin type I
- Recurrent HSV skin infections
- Hypertrophic scars
- Keloid
- Cardiac 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 involves
- 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):	24-02-2017

Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	ReNovaCell kit
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-10-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-05-2018
Application type:	Amendment
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	NL57683.018.16