Early clinical and biomarker responses after treatment in patients with non-segmental vitiligo

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- Assess whether early markers (in blood and/or skin) can predict the clinical response to treatment (i.e. surface area of repigmented skin after 3 and 6 months of standard of care treatment).- Assess the relation between markers in blood, skin...

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

Summary

ID

NL-OMON48618

Source
ToetsingOnline

Brief title
Early responses in vitiligo

Condition

- Pigmentation disorders

Synonym
Vitiligo

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Novartis Institutes for BioMedical Research

Intervention

Keyword: Biomarkers, Dermatology, Vitiligo

Outcome measures

Primary outcome

1. Clinical non-invasive parameters

Surface area of depigmented skin will be assessed at Baseline, and after 3 months and 6 months of treatment from a target lesion (copy sheet method) and from the total body (VES score and VASI score) to determine the extent of the disease.

2. Laboratory parameters

-Biomarkers will be assessed from blood, suction blister fluid and punch biopsies at Baseline and after 3 months of treatment.

3. Imaging

-Confocal reflectance microscopy imaging will be used for non-invasive imaging of melanocytes and inflammatory cells in vitiligo.

-Digital imaging of the target lesion.

4. Patient Reported Outcomes (PROs)

-The DLQI questionnaire will be used to collect Quality of Life data at Baseline, 3 months and 6 months after treatment.

-The PHQ-9 will be used to collect data on the impact of vitiligo on the

presence and severity of depression.

Secondary outcome

-

Study description

Background summary

Non-segmental vitiligo (NSV) is a chronic autoimmune disorder leading to destruction of melanocytes. The depigmentation in vitiligo is caused by autoimmune reactions against melanocytes, including specific T cell and antibody responses. Several factors including biochemical, neuronal and environmental may contribute to the development of the autoimmunity in vitiligo.

Vitiligo is sometimes considered to be merely a cosmetic problem. However, its psychosocial impact and social stigmatization in various societies must not be neglected. Multiple studies show a significant negative effect of vitiligo on the quality of life. The importance of treatment is often underestimated due to the lack of recognition of the impact of the disease for patients.

So far, the treatment of vitiligo still remains a challenge. There is no curative treatment available for NSV. Current treatments include topical agents, phototherapy and surgical techniques which aim to improve melanocyte proliferation and stimulate repigmentation. However, these interventions are not satisfactory in all patients as complete repigmentation is usually not achieved.

Due to the unsatisfactory and limited treatment options there is a crucial need to identify biomarkers of disease activity to support clinical trials for vitiligo. Different biomarkers have been reported to be linked to the disease activity and autoimmune process in NSV. However, comprehensive studies comparing these biomarkers in different tissues are not available. Moreover, the relation between these biomarkers and repigmentation resulting from different treatments is unclear. We hypothesize that some biomarkers may predict the response to treatment.
Our research depends on the availability of bodily material (blood, skin and suction blister fluid) of vitiligo patients. Furthermore, we will assess the quality of life and psychosocial changes during treatment using patient-reported outcome questionnaires.

Study objective

- Assess whether early markers (in blood and/or skin) can predict the clinical response to treatment (i.e. surface area of repigmented skin after 3 and 6 months of standard of care treatment).

- Assess the relation between markers in blood, skin biopsy and suction blister fluid.

- Investigate the use of non-invasive confocal reflectance microscopy imaging as well as imaging based on digital photography to assess early clinical response.

- Assess psychosocial changes during treatment using patient-reported outcomes by assessing the impact of vitiligo on quality of life factors (using the Dermatology Quality of Life Questionnaire [DLQI]) and depression (using the Patient Health Questionnaire * 9 [PHQ-9]).

Study design

Prospective cohort study in patients with non-segmental vitiligo who receive standard of care treatment.

Study burden and risks

The standard of care treatment will not be changed or influenced by participation in the study. Standard of care treatment will be prescribed to the patients prior to enrolment into the study, based on the prescribing physician*s medical assessment.

The time investment for the patient will be approximately 120 minutes for each of the first two visits. The last visit could take place on the same day of the routine control in patients receiving treatment for their vitiligo and will be approximately 30 minutes.

Risks for the patients due to sampling procedures are minimal. Blood sampling will occur at Baseline and at 3 months of treatment, at which a maximum volume of 50 ml of blood will be collected at each visit. Vena puncture to draw blood can result in a hematoma at the site of puncture.

Suction blisters are extremely superficial (150 µL µm) and usually heal without a scar. However, pigmentation changes may occur that generally resolve within 12 months. Fluid from suction blisters will be collected at Baseline (2 suction blisters) and at 3 months (1 suction blister).

Skin punch biopsies are routine diagnostic procedures in dermatology and leave mild textural changes, which can be minimized when a suture is applied after harvesting. The risk of infections due to these procedures is minimal (< 1 %).

Punch biopsies (4 mm diameter) will be collected at Baseline and at 3 months.

There is no benefit expected for patients participating in this study. This study may help in identifying early markers for treatment response and could therefore be important to identify non-responders at an early stage. Moreover, this study will contribute to the knowledge on the pathogenesis of vitiligo. *

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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 commencing standard of care treatment, consisting of a potent topical corticosteroid, such as FP cream, alone or in combination with NB-UVB phototherapy for at least 6 months.
- Patients with new lesions and/or signs of disease progression (active

disease) within the past 6 months prior to Screening.
- Males and females aged *18
- Patients able to communicate well with the investigator, to understand the requirements of the study, as well as understand and sign the written informed consent.

Exclusion criteria

- Patients that have received phototherapy or systemic immunosuppressive treatment during the last 6 weeks prior to Screening.
- Patients that have received topical anti-inflammatory treatment (topical corticosteroids, calcineurin inhibitors) during the last 4 weeks prior to Screening.
- Patients currently receiving treatments other than potent topical corticosteroids, such as FP 0.05% cream, calcineurin inhibitors (tacrolimus, pimecrolimus) or NB-UVB phototherapy for non-segmental vitiligo.
- Recurrent HSV skin infections.
- Patients with a history of hypertrophic scars or keloid.
- Patients with a history of hypersensitivity to (UVB or UVA) light and/or allergy to local anaesthesia.
- Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive hCG laboratory test (unless female is confirmed post-menopausal).
- Patients with haemophilia or other clotting disorders
- Patients previously diagnosed with depression according to the DSM5 by a qualifying physician.
- Patients without lesions located at suitable areas for biopsies / suction blisters sampling (e.g. the face)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2019
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	15-01-2019
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	NL66309.018.18