Handheld Laser Speckle Contrast Imaging Device for optical microcirculatory perfusion imaging: Clinical, therapeutic and pathophysiological implications for adult- and paediatric psoriasis.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON48499

Source
ToetsingOnline

Brief title
Handheld Laser Speckle Contrast Imaging in psoriasis.

Condition

- Epidermal and dermal conditions

Synonym
Psoriasis

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO domein Toegepaste en Technische Wetenschappen (TTW);projectnummer 14538

Intervention

Keyword: Diagnostic imaging / Perfusion imaging, Microcirculation, Psoriasis, Skin

Outcome measures

Primary outcome

The main study endpoints will be:

1. Visualization of vascular involvement as measured by perfusion intensity in the pathogenesis of psoriasis with the Handheld LSCI Device in both adult and paediatric psoriasis patients.

2. The detection of *hot-* and *cold spots* within a psoriatic lesion using the Handheld LSCI Device in both paediatric and adult patients.

3. Identification of vascular involvement in the pre-psoriatic skin and predicting development and expansion of psoriasis plaques with the Handheld LSCI Device in both paediatric and adult patients.

Secondary outcome

The secondary study endpoint will be:

1. Comparison of the transcriptome signatures of *hot spots*, *cold spots*, pre-psoriatic skin and post psoriatic skin as identified with the Handheld LSCI Device.

Study description

Background summary

The process of angiogenesis is a key phenomenon in the development of psoriasis and is considered to indicate early development of new psoriatic lesions. In this study we will focus on these (early) detectable changes in the microcirculation of the psoriatic skin, and more particularly on the predictive value of these changes on the course of the disease. The non-invasive Handheld Laser Speckle Contrast Imaging (LSCI) Device, which measures perfusion intensity, could be used in future as a non-invasive method to predict treatment outcome, disease development and progression of psoriasis. Our research could have an impact on clinical (prediction of development of psoriasis plaques), therapeutic (preventive treatment, new therapeutic targets) and pathophysiological (psoriasis transcriptome) level.

Study objective

Our objectives in both adult and paediatric psoriasis patients are (I) To validate the Handheld LSCI Device for visualization of vascular changes within psoriatic plaques. (II) Identification of the most active and least active sides of psoriatic lesions as measured by the Handheld LSCI Device. (III) To test whether the Handheld LSCI Device may reveal the dynamics of the early changes in microcirculation on the transition from clinically normal skin into psoriatic lesions. As a secondary objective we will compare the transcriptome signatures of *hot spots*, *cold spots*, pre-psoriatic skin and post psoriatic skin in adult patients.

Study design

The study is partly interventional and partly observational using the non-invasive Handheld LSCI Device to investigate microcirculation changes in both adult and paediatric psoriasis.

Intervention

Our study will consist of three research cohorts. In cohort 1 (n=8) the natural course of psoriasis and the development of psoriasis plaques will be observed by scanning an untreated body area with the Handheld LSCI Device. In patients in cohort 2 (n=8) the expansion and clearance of psoriasis lesions (induced by clobetasol ointment), will be observed. Biopsies will be taken from different perfusion areas within lesions. In adult patients, follow up will take up to 8 weeks. Paediatric patients (n=3) in cohort 3 will be scanned with the Handheld LSCI Device during 2 regular outpatient clinic visits.

Study burden and risks

There are no immediate benefits for subjects participating in the study, but this study could unravel new therapeutic targets or strategies. Given the non-invasive nature of the Handheld LSCI Device we estimate the study risks as *negligible*. Scanning the skin using the Handheld LSCI Device is painless and without any discomfort. The punch biopsies for RNA isolation, and immunohistochemistry are taken according to standard procedure and may be slightly tender. Scar formation is barely visible.

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

Cohort 1 (8 patients):
To enter into this study patients must meet the following criteria:
* * 18 years of age.
* Patients with a diagnosis of unstable plaque psoriasis according to a dermatologist.
* Patients on topical treatment, who are not eligible or willing to receive systemic anti-psoriatic treatment.
* Patients must be willing to discontinue their topical treatment on one body area for a maximum of eight weeks.
* Patients must be willing to give a written informed consent.
* Patients must be able to adhere to the visit schedule.;Cohort 2 (8 patients):
To enter into this study patients must meet the following criteria:
* * 18 years of age.
* Patients with a diagnosis of plaque psoriasis according to a dermatologist.
* Patients who are on topical treatment.
* * two clinically visible plaques with a minimal diameter of three centimetres.
* Patients must be willing to discontinue topical treatment of two plaques for respectively two and a maximum of ten weeks.
* Patients must be able to adhere to the visit schedule.
* If applicable: patients must be willing to switch topical therapy for one psoriasis plaque to clobetasol ointment for a maximum of eight weeks.
* Patients must be willing to undergo six skin biopsies.
* Patients must be willing to give a written informed consent.;Cohort 3 (3 patients):
To enter into this study paediatric patients must meet the following criteria:
* Aged * 6 and < 18 years.
* Patients who are on topical psoriasis treatment or on stable doses of systemic anti-psoriatic treatment.
* Paediatric patients and/or their guardians must be willing to give a written informed consent.

Exclusion criteria

Cohort 1:
* Patients with stable plaque psoriasis according to a dermatologist.
* Patients with a history or signs of other inflammatory skin diseases, for example atopic dermatitis.
* Patients on systemic anti-psoriatic treatment.
* Patients unwilling or unable to give informed consent.;Cohort 2:
Patients will be excluded from this study when any of the following criteria listed below are met:
* Patients with a history or signs of other inflammatory skin diseases, for example atopic dermatitis.
* Patients on systemic anti-psoriatic treatment.
* Patients with a known Koebner phenomenon.
* Patients unwilling or unable to give informed consent.;Cohort 3:
* aged <6 or *18 years of age.

* Patients with a history or signs of other inflammatory skin diseases, for example atopic dermatitis.
* Patients using varying doses of systemic anti-psoriatic treatment (like methotrexate or biologics). Doses have to be stable for at least three months.
* Patients in which the dose of systemic treatment is likely to change over the next three months.
* Patients or parents unwilling or unable to give informed consent.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2019
Enrollment:	19
Type:	Actual

Medical products/devices used

Generic name:	Handheld Laser Speckle Contrast Imaging Device
Registration:	No

Ethics review

Approved WMO Date:	23-04-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-08-2019

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL69174.091.19