Evaluation of the use of biomarker levels in dried blood spots as a measurement tool for disease severity in patients with atopic dermatitis and psoriasis.

Published: 11-02-2015
Last updated: 21-04-2024

To investigate whether the levels of a panel of biomarkers in dried blood spots can be used as a disease severity measurement tool in patients with AD or psoriasis.

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

Summary

ID

NL-OMON41918

Source
ToetsingOnline

Brief title
Dried blood spots in atopic dermatitis and psoriasis.

Condition

- Epidermal and dermal conditions

Synonym
atopic dermatitis, atopic eczema, eczema, psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atopic dermatitis, Biomarkers, Dried blood spots, Psoriasis

Outcome measures

Primary outcome

- Levels of 7 biomarkers determined from DBS (three time points)

- Disease severity measured by POEM / SA-PASI (patient). (three time points)

- Disease severity measured by EASI / PASI (physician). (three time points)

Secondary outcome

Not applicable.

Study description

Background summary

Atopic dermatitis (AD) and psoriasis are common chronic inflammatory skin diseases with a relapsing and remitting pattern. Promising new treatments for atopic dermatitis and psoriasis are currently investigated. An important question will be whether they are more effective than established treatments such as cyclosporin A. However, comparing the results of (different) clinical trials is often difficult because of the large number of clinical outcome measures that are being used.
Many severity measurement tools that are used in clinical trials have not been validated. A recent review concluded that the Eczema Area and Severity Index (EASI), the SCORing Atopic Dermatitis (SCORAD) and the Patient Oriented Eczema Measure (POEM) are currently the best validated instruments to assess the severity of AD. The Psoriasis Area and Severity Index (PASI) and the self-assesed PASI (SA-PASI) are the most widely used clinical trial efficacy end points for psoriasis. However, the use of these instruments is time consuming and the ultimate goal from the perspective of evidence-based medicine is to achieve worldwide consensus to consistently apply a single valid, reliable, and feasible instrument to measure disease severity of AD and psoriasis in all future clinical trials. Therefore, there is an urgent need for a valid, reliable and objective severity measurement tool.
The discovery of novel cytokines and chemokines generated new potential biomarkers. A large number of these serum biomarkers have been found to correlateto disease severity in AD. The most frequently reported serum

biomarkers for AD include serum ECP, serum IgE, serum IL-2R, and serum TARC/CCL17 levels. Currently, no biomarkers are used for monitoring disease severity in psoriasis.
A disadvantage of the use of serum biomarkers is the need for a venipuncture, that can only be performed by trained personnel. We therefore want to investigate the correlation of the levels of a panel of biomarkers determined in dried blood spots (DBS) with disease severity. Collection of a DBS is a relatively simple and minimally invasive, nearly painless procedure that can be done by the patients themselves, at home. We suggest that biomarkers determined in DBS can replace the assessment of disease severity by clinical severity measurement tools. This will have great advantages for both daily practice and clinical trials. It offers an objective measurement tool for disease severity in AD and psoriasis, which will improve monitoring of patients and make outcome measures in clinical trials more comparable. Moreover it will decrease the burden of disease, because less visits to the hospital are necessary. Also in daily practice this will give us an objective tool to monitor the effects of treatments/interventions.

Study objective

To investigate whether the levels of a panel of biomarkers in dried blood spots can be used as a disease severity measurement tool in patients with AD or psoriasis.

Study design

Time point 1: visit to the outpatient clinic.
-the researcher explains how to obtain a DBS,
-DBS sampling,
-disease severity measurement by the patient using POEM/SA-PASI,
-disease severity measurement by the clinician using EASI/PASI,
-the DBS is brought to the laboratory by the research-physician.

Time point 2: visit to the outpatient clinic, 3 weeks after visit 1.
-DBS sampling,
-disease severity measurement by the patient using POEM/SA-PASI,
-disease severity measurement by the clinician using EASI/PASI,
-the DBS is brought to the laboratory by the research-physician.

Time point 3: visit to the outpatient clinic, 6 weeks after visit 1.
-DBS sampling,
-disease severity measurement by the patient using POEM/SA-PASI,
-disease severity measurement by the clinician using EASI/PASI,
-the DBS is brought to the laboratory by the research-physician.

Study burden and risks

Participants will undergo a finger prick in three sessions. Performing a fingerprick entails a slight risk of haemorrhage and infection. The fingerprick is comparable to the routinely obtained fingerpricks by diabetic patients at home.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-over 18 years of age
-diagnosis of AD (according to the criteria of Hanifin and Raijka) or diagnosis of psoriasis
-treatment with topical steroids

Exclusion criteria

Treatment with systemic corticosteroids or other immunosuppressive medication within the 4 weeks prior to obtaining the DBS.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2015
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	11-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-01-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL51139.041.14