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

Published: 11-08-2014
Last updated: 20-04-2024

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, treated with topical steroids.

Ethical review	Not approved
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON41002

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 biomarkers determined from DBS (three time points)

- Disease severity measured by POEM / SA-PASI. (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 EASI and SCORAD are currently the best validate instruments to assess the severity of AD. The Psoriasis Area and Severity Index (PASI) are the most widely used clinical trial efficacy end point for psoriasis. However, intraobserver reliability of these type of instruments remains unclear and the instruments are time consuming. Therefore, there is an urgent need for valid, reliable and objective severity measures that allow comparison of clinical trials and epidemiological studies.
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.
The disadvantage of the use of serum biomarkers is the need for a venipuncture. This is invasive and only possible during admission or control visits. We

therefore want to investigate the levels of a panel of biomarkers, determined in dried blood spots (DBS). Collection of 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 dried blood spots will replace the currently used serum biomarkers. 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. Moreover it will decrease the burden of disease, because less visits to the hospital are necessary.

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, treated with topical steroids.

Study design

1. Time point 1: visit to the outpatient clinic.
- the researcher explains how to obtain a dried blood spot,
- the patient conducts a small amount of blood by a fingerprick, this is blotted and dried on filter paper,
- disease severity measurement by POEM / SA-PASI.

2. Time point 2: t=14 days after visit 1.
- the patient conducts a small amount of blood by a fingerprick, this is blotted and dried on filter paper,
- disease severity measurement by POEM / SA-PASI.

3. Time point 3: During exacerbation.
- the patient conducts a small amount of blood by a fingerprick, this is blotted and dried on filter paper,
- disease severity measurement by POEM / SA-PASI.

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

-age 18-70 years
-diagnosis of atopic dermatitis(according to the criteria of Hanifin and Raijka) or diagnosis of psoriasis
-treated with topicol steroids

Exclusion criteria

Treatment with systemic corticosteroid 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:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Not approved

Date:	11-08-2014
Application type:	First submission
Review commission:	METC NedMec

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	NL47641.041.14