Biophysical measurements and correlation with clinical parameters for stratification of atopic dermatitis in children

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To investigate whether atopic dermatitis patients can be stratified based on integral analysis of clinical patient data complemented by novel biophysical measurements, in-vivo Raman spectroscopy, microbiome swabs and a oral mucosa swab (one time).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON46685

Source
ToetsingOnline

Brief title
Stratification of atopic dermatitis in children

Condition

- Epidermal and dermal conditions

Synonym
Atopic dermatitis, eczema

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atopic dermatitis, Microbiome, Raman spectroscopy, Stratification

Outcome measures

Primary outcome

Correlation between clinical patient data and LPR (Measured with Raman Spectroscopy)

Secondary outcome

Correlation between clinical patient data and Natural Moisterizing Factor (NMF), measured with Raman Spectropscopy

Correlation between clinical patient data and alterations in skin microbiome

Correlation between clinical patient data and alterations in nose microbiome

Integral correlation between clinical patient data and all biophysical measurements

Study description

Background summary

Stratification of atopic dermatitis patients is relevant to improve health care for these patients. This is a prospective study. For this study, in vivo Raman spectroscopy measurements on the skin of patients will be performed to determine the lipid-to-protein ratio (LPR) in the skin, microbiome swabs will be taken of the skin and mucosa of the nose and oral mucosa swabs will be taken for fillagrin DNA analysis. It is expected that the biophysical measurements can be associated with clinical aspects of the disease, under which disease severity, and can therefore provide new possibilities for stratification of patients.

Study objective

To investigate whether atopic dermatitis patients can be stratified based on integral analysis of clinical patient data complemented by novel biophysical measurements, in-vivo Raman spectroscopy, microbiome swabs and a oral mucosa swab (one time).

Study design

prospective observational study.

Study burden and risks

The biophysical measurements done during this study are non-invasive, painless and not harmful. Skin and nose swabs for microbiome analysis and the oral mucosa swab take around three minutes. In vivo Raman spectroscopy measurements for determination of LPR take in total approximately 15 minutes, during which the patient has to sit still during each repeat measurement of about one minute. The risks associated with participation are negligible. Because atopic dermatitis is a disease mainly affecting children it is important to investigate possible parameters in especially this group of patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Aged between 0-18 years
Indication of atopic dermatitis

Exclusion criteria

No informed consent.
Patients and their parents or guardian do not speak Dutch.
Patients and their parents or guardian have no access to internet or are not able to use the online questionnaires.
Applying ointments or oil on the skin of the arm and hand on the day of visit to the dermatologist

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-10-2017
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	08-09-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-04-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL62118.078.17