CytoKine measurement in Skin WaShfluid

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Upregulation of the inflammatory response in skin of patients with atopic dermatitis, psoriasis or cutaneous LE coincides with the expression and secretion of a distinct set of proinflammatory markers, including cytokines, chemokines and soluble...

Ethical review	Approved WMO
Status	Pending
Health condition type	Allergic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON57070

Source
ToetsingOnline

Brief title
KISS

Condition

- Allergic conditions

Synonym
atopic dermatitis (eczema), cutaneous LE (lupus), psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Convergence Health and Technology

Intervention

Keyword: Inflammation, Skin immune mediators, Skin wash device

Outcome measures

Primary outcome

Cytokine concentration in skin wash of healthy controls and dermatology

patients.

Secondary outcome

NA

Study description

Background summary

Exposure to air pollution, such as ozone (O3), particulate matter (PM), carbon monoxide (CO), sulfur dioxide (SO2), and nitrogen dioxide (NO2) is strongly associated with development of diseases of the respiratory tract, the skin and the eyes. We aim to characterize immune mediators in healthy and inflamed skin, to identify immune-related biomarkers of interest to study in the context of air pollution. We propose to develop a system that enables measurement of immune mediators in skin in a non-invasive manner. As a prove of principle, we chose to focus first on three pathological skin conditions that differ in underlying immune pathogenesis and associated cytokines: 1) atopic dermatitis (AD), a Th2-driven condition; 2) psoriasis, a Th17-driven condition and 3) cutaneous SLE (CLE), a Th1-skewed interferon-driven disease and healthy controls. Currently used methods to measure biomarkers in the skin include tape stripping, and collecting suction blister fluid, both invasive methods. We propose to use a customized skin wash device to non-invasively collect biomarkers from skin in a reproducible manner.

Study objective

Upregulation of the inflammatory response in skin of patients with atopic dermatitis, psoriasis or cutaneous LE coincides with the expression and secretion of a distinct set of proinflammatory markers, including cytokines, chemokines and soluble receptors. We aim to develop a non-invasive method to collect skin immune mediators.

Primary objectives:
1. To provide proof-of-principle of the skin wash system using recombinant protein.

2. To identify biomarkers in skin of patients with atopic dermatitis, psoriasis and cutaneous LE using our skin wash system.

Study design

1. To provide proof-of-principle of the skin wash system using recombinant protein.
To show that we can successfully elute biomarkers of interest from the skin of healthy controls, we will apply recombinant cytokine solution (IL-1β, IL-6, IL-8, IL-10, IL-18 and TNFα) to the forearm skin of healthy control volunteers (n=5). The solution will be allowed to dry, before placing the skin washer: the well is attached to the arm using an adjustable bracelet. Cold PBS/0.05% T-20 containing the capture beads is added for 30 minutes and the well is closed with a screw cap. Wash solution will be collected after 30 minutes and analysed for the cytokines with Luminex technology. Only if we can successfully detect the recombinant cytokines we move to objective 2.

2. To identify biomarkers in non-invasive skin washes of patients with atopic dermatitis, psoriasis and cutaneous LE
We aim to include n=10 healthy controls, n=10 atopic dermatitis patients, n=10 psoriasis patients and n=10 cutaneous LE patients.
Patients and healthy controls will be asked to wear the skin wash device on lesional skin (for patients) and on non lesional skin (both patients and healthy contols), to demonstrate specific patterns of immune mediator expression associated with AD. Psoriasis and CLE.
As described before, the well is attached to the arm using an adjustable bracelet. Cold PBS/0.05% T-20 containing the capture beads is added for 30 minutes and the well is closed with a screw cap. Cytokine levels are determined with luminex technology.

Study burden and risks

Participants will wear our skin wash device for 30 minutes, there is no risk associated with wearing it, and no discomfort is expected.
Although we do not expect this, mild and transient skin irritation might be caused by the recombinant protein. If this occurs, the even twill be reported.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy controls must:
- Be immunologically healthy (no known immunopathology)
- Be non-obese
- Not use prescription medication (with the exception of oral contraceptives)
- Be aged >18
- Be willing and able to give written informed consent
- Be employed by ErasmusMC

Patients must:
- Be diagnosed with AD, psoriasis, or CLE
- Be >18 years old
- Have no known co-morbidities
- Be willing and able to provide written informed consent

Exclusion criteria

Exclusion criteria healthy controls:
- Immunological disease, (seasonal) allergy
- Malignant disease

- Medication use (exception oral contraceptives)- BMI >25
- Unable or not willing to provide informed consent
- Under direct supervision of the principal or coordinating investigator, or a student/intern

Exclusion criteria patients :
- Known co-morbidities
- Malignant disease
- BMI >25
- Unable or not willing to provide written informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-12-2024
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Skin wash sampler
Registration:	No

Ethics review

Approved WMO

Date:	28-10-2024
Application type:	First submission
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	NL87072.078.24