Better control and treatment of Atopic Dermatitis disease by exploring the universe of microenvironment imposed tissue signatures and their correlates in liquid biopsies

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To collect prospective clinical and molecular data on the phenotypical characteristics of patients with atopic dermatitis (AD) receiving standard care targeted systemic treatment.

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

Summary

ID

NL-OMON51252

Source
ToetsingOnline

Brief title
ImmUniverse WP6 AD

Condition

- Epidermal and dermal conditions

Synonym
eczema, topic dermatitis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: EFPIA: European Federation of Pharmaceutical Industries and Associations,Europese Unie: Horizon 2020 project: Innovative Medicines Initiative 2 Joint Undertaking

Intervention

Keyword: Atopic dermatitis, Skin biopties, Tissue signatures

Outcome measures

Primary outcome

Molecular stratification tools and *hard* molecular endpoints for disease

control on the

individual patient level.

Aanalysis of tissue-derived signatures with *circulating signatures* detectable

in liquid biopsies (bood and tissue liquids), employing state-of-the-art

profiling technologies corresponding to multi-Omics datasets.

Secondary outcome

Not applicable.

Study description

Background summary

Immune-mediated diseases are extremely diverse - patients with the same diagnosis may see the disease progress in very different ways, and respond differently to treatments. This is because the course of the disease is influenced by multiple factors, including the patient*s genes, immune system, environment, and the microbes living in their gut. Furthermore, all of these factors interact with and impact on one another. As a result, it is very hard to predict how the disease will develop in a specific patient, and which treatments will be effective.

The goal of the ImmUniverse WP 6 AD study is to add to our understanding of the immune-mediated disease atopic dermatitis (which affects the skin). It will use liquid biopsies to detect the immune cells circulating in the blood, and analyze how these interact with the tissues affected at the microenvironment scale.

The project*s findings should contribute to a better, more precise diagnosis for patients; and better information on how severe the disease is likely to be for each individual patient and how it will progress over time. Finally, the project will make it easier for doctors and patients to monitor how well a treatment is working in the future.

Study objective

To collect prospective clinical and molecular data on the phenotypical characteristics of patients with atopic dermatitis (AD) receiving standard care targeted systemic treatment.

Study design

This is an open label, non-blinded, prospective study in which targeted therapies are administered as part of standard healthcare and which aims at identifying prognostic and therapeutic biomarkers associated with disease activity, progression and response to therapy.

This is an observational trial in which licensed and available therapies are used as per label. Patient eligibility is according to standard of care as laid down in the SmPC. A key inclusion criterion is the prescription of a targeted therapy (i.e. kinase inhibitor or biologic). Choice of medications (which are all approved for first line use) is by treating physicians. It may be random but is not randomized. Most of the follow-up procedures are according to standards of care. Except for the biosampling at three timepoints during this study. Standardized routine visits are performed to document patient characteristics as well as physician- and patient-reported outcomes.

The patients will be recruited in a long-term follow up scheme, which comprises an at least 12 month follow up for disease activity (PRO, biopsy, inflammation markers etc. as outlined above) and where possible a further 24 month follow up for assessment of disease course and complications (patient interview). Baseline and follow up visits will include biopsy procedures and blood samples.

Study burden and risks

In general, we expect the risks for participation to be negligible. Skin biopsies pose a small risk of (excessive) post biopsy bleeding, infection of the biopsy wound and scar formation. However, despite being performed on large

scale in daily dermatology practice, severe complications are hardly ever encountered. Post biopsy bleeding is prevented by applying adequate pressure to the biopsy wound after the skin sample is taken. Infection prevention includes the use of packed sterilized punch biopsy devices and disinfection of the body site with alcohol before the biopsy is taken. Patients with a tendency to develop hypertrophic scars will be excluded to prevent excessive scarring.

The extra vials of blood will be drawn from the patients at moments when blood is already drawn for usual care.

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

1. Age >= 18 years at time of study entry

2. Written Informed Consent.
3. Diagnosis of chronic atopic dermatitis for at least 1 year prior to enrollment
4. Use of licensed targeted immuno therapy within routine care

Exclusion criteria

1. Experiencing or history of other concomitant skin condition that would interfere with evaluations of the effect of medication on atopic dermatitis.
2. Patients with a tendency to develop hypertrophic scars

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-06-2022
Enrollment:	60
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	28-09-2021
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-01-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-06-2024
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	NL76628.091.21