ImmUniverse Work Package 5 AD: 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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The main aim of this project is to obtain a better control and treatment of immune-mediated diseases by exploring the universe of microenvironment imposed tissue signatures and their correlates in liquid biopsies.

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

Summary

ID

NL-OMON49924

Source
ToetsingOnline

Brief title
ImmUniverse WP5 AD

Condition

- Epidermal and dermal conditions

Synonym
atopic dermatitis, psoriasis

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 Inniative 2 Joint Undertaking

Intervention

Keyword: Atopic Dermatitis, Psoriasis, Skin Biopties, Tissue signature

Outcome measures

Primary outcome

The main aim of this project is to obtain a better control and treatment of

immune-mediated diseases by exploring the universe of microenvironment imposed

tissue signatures and their correlates in liquid biopsies

Secondary outcome

There is no secondary outcome of the study.

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.
Hence, mechanistic understanding of this heterogeneity and biomarkers predictive for disease control and therapy response over time are important prerequisites of a future precision medicine in IMIDs. ImmUniverse has been formed as a European transdisciplinary consortium to tackle these unmet needs and to understand the role of the crosstalk between tissue microenvironment and

immune cells in disease progression and response to therapy of ulcerative colitis (UC) and atopic dermatitis (AD).
The consortium will combine analysis of tissue-derived signatures with *circulating signatures* detectable in liquid biopsies, employing state-of-the-art profiling technologies
to provide new validated diagnostics in IMID that are expected to improve patient management, lead to increased patient well-being and will significantly reduce the socioeconomic burden of these diseases.
Immuniverse Work Package 5 (WP5) will validate the disease pathway -and mechanism signatures identified in the multi omic discovery WP2 in immune cells in affected tissue and peripheral blood. WP5 aims to further substantiate our understanding of the immune-mediated skin disease atopic dermatitis (AD). The skin mediated immune disease Psoriasis that has a different immunopathology will be used for reasons of comparison. WP5 will use liquid biopsies (peripheral blood) and affected skin biopsies to generate transcriptome, proteome, DNA-methylome and miRNA signatures of immune cell subsets and analyse the association between immune cells circulating in peripheral blood and the microenvironment of affected skin tissue
Also this WP aims to develop a protocol to analyse and sort living immune cells from cryopreserved tissue. Ultimately, 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. The project overall aim is to improve disease stratification, successful treatment selection and therapy follow-up (early detection of side effects or non-responsiveness).

Study objective

The main aim of this project is to obtain a better control and treatment of immune-mediated diseases by exploring the universe of microenvironment imposed tissue signatures and their correlates in liquid biopsies.

Study design

This is a study in which patients donate extra blood and skin biopsies once during a regular outpatient clinic visit.

Intervention

Taking 2 biopsies. 1 of 3x3 mm and one of 4x4 mm.
3 extra tubes of blood are drawn during regular blood collection.

Study burden and risks

The patients are seen during their regular outpatient visits.
By taking the 2 biopsies, this visit will take 20 minutes longer than normal.

We do not expect any complications when taking the biopsies.
The collection of 3 extra blood tubes will be done during regular blood tests.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Diagnosis of Atopic Dermatitis or Psoriasis
Age >= 18 years
Provide signed informed consent

Exclusion criteria

Age <= 18 years

Likely to develop hypertophic scars
Unable to give informed consent

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-04-2022
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	12-01-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-05-2022
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	NL78274.091.21