Biomarkers in Atopic Dermatitis and Psoriasis The Netherlands

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

Summary

ID

NL-OMON48036

Source
ToetsingOnline

Brief title
BIOMAP NL

Condition

- Epidermal and dermal conditions

Synonym
Atopic dermatitis, atopic eczema

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: IMI2-2017-13-02: Genome-Environment Interactions in Inflammatory Skin Disease.

Intervention

Keyword: Atopic dermatitis, Biomarkers

Outcome measures

Primary outcome

The combined efforts of BIOMAP will support the definition of endotypes, i.e. a more precise disease classification, a definition of biomarkers enabling patient stratification and patient-directed care strategies, and the early identification of the most suitable therapy for every patient.

Secondary outcome

BIOMAP will also stimulate future research on mechanisms and innovative treatments directed at endotype components.

Study description

Background summary

Atopic dermatitis (AD) and psoriasis (Pso) are common inflammatory skin disorders. They are heterogeneous diseases comprising a variety of subtypes, which share common clinical characteristics but arise from distinct and definable molecular and cellular mechanisms, i.e. endotypes, some of which might overlap. Understanding these shared and exclusive mechanisms will lead to the identification of biomarkers for patient stratification, and enable reasonably accurate prediction of disease onset, progression and response to therapy for appropriate selection of type and timing of intervention (decision support) to reach a high degree of disease control (across patients and within individuals).

Study objective

BIOMAP (Biomarkers in Atopic Dermatitis and Psoriasis) NL is part of the BIOMAP consortium, which is a EU-funded consortium through which various research projects will address three main unmet needs in AD and Pso with a broad impact on disease management, patient-directed care strategies and future trial designs: (a) Identification of major determinants of manifestation, progression

and comorbidity development; (b) Improved understanding of shared and distinct disease mechanism(s) and associated signatures, and their relative importance in patient subpopulations; and (c) Identification of objective markers capable of assessing disease-related individual patient trajectories and response to different therapies. BIOMAP NL will only perform research in the field of atopic dermatitis.

Study design

BIOMAP is a collaborative network of clinicians, researchers and industry along with patient organisations and other major stakeholders. The BIOMAP project has achieved the Consortium Agreement and Grant Agreement has been signed (call: IMI2-2017-13-02: *Genome-Environment Interactions in Inflammatory Skin Disease*). It will start on April 1st 2019. The Amsterdam UMC location AMC is part of this consortium (BIOMAP NL) and will contribute patient data, biopsies, blood samples and tape strips of AD patients (not Pso) to the consortium. Data and biosamples will be collected from AD patients participating in the TREAT NL (TREatment of ATopic eczema, the Netherlands) registry. The TREAT NL registry is a non-WMO registry (W18_097 # 18.123).

Study burden and risks

Patients will be asked permission for the collection of body material and can indicate themselves which and how much body material they are willing to donate. The body material will be collected following their usual appointment in the hospital. It concerns the collection of blood (a maximum of 8 tubes of a maximum of 9 ml blood, at a maximum of 5 sampling points). In patients receiving systemic treatment this extra amount of blood will be obtained during the regular blood collection. Secondly, patients of 16 years and older can participate in the collection of skin biopsies. Under local anesthesia, a round piece of skin of up to 4 mm in diameter is removed from a spot that is cosmetically acceptable. A maximum of 2 skin biopsies (lesional and non-lesional skin) will be taken at a maximum of two collection time points (baseline and after 3 months of treatment). Thirdly, tape strips will be collected. Tape stripping is a painless non-invasive method where round stickers of 3.8 cm2 are applied to the skin for 10 seconds and then removed from the skin. Per visit a maximum of 8 consecutive tape strips will be collected from a spot with eczema and a maximum of 8 tape strips from a spot without eczema, preferably at the location of the forearm, at a maximum of 5 sampling points.

Participation in the collection of body material may cause discomfort:
- Blood: the procedure is a standard venipuncture. Blood sampling can be painful to a limited extent or cause a bruise afterwards. For patients on systemic treatments blood collection will occur anyhow in the context of standard care. Patients receiving phototherapy will be asked if they are

willing to donate blood.
- Skin biopsy: the injection for the anesthesia of the skin is a bit painful; if desired, extra an-aesthesia of the skin by applying an anesthetic ointment 30-60 minutes prior to the biopsy can be possible. Collection of the biopsy thereafter is pain-free. There is a small chance of a short-term bleeding. The small round wound in the skin will generally heal to a discrete scar. In rare cases, inflammation of the wound can occur and the scar becomes less attractive.
- Tape strips: after the sample collection the skin may temporarily be slightly redder than normal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patients with atopic dermatitis participating in the TREAT NL registry.
Patients can be part of the TREAT NL registry if they have atopic dermatitis AND start with a systemic immunomodulating treatment or phototherapy in the context op standard patient care

Exclusion criteria

No participation in the TREAT NL registry, patients not recieving systemic immunomodulating treatment or phototherapy as treatment for their eczema

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2020
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	19-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21253
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL69586.018.19