BIOMAD NL study

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The precise mechanisms driving onset and course are insufficiently understood, disease progression from a current patient state and/or the development of comorbidities are unpredictable, and the optimal type and time-point for intervention is as yet...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21253

Bron
Nationaal Trial Register

Verkorte titel
BIOMAD NL

Aandoening

Atopic dermatitis, atopic eczema

Ondersteuning

Primaire sponsor: Amsterdam UMC, Academic Medical Center
Overige ondersteuning: Innovative Medicines Initiative (IMI)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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. They will also stimulate future research on mechanisms and innovative treatments

directed at endotype components.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

TREAT Germany, A*Star (UK) and TREAT NL are three sister registries assessing the same patient population and outcomes and collecting the same type of biosamples. The coordinating centers of these registries including AMC are partners within the EU-IMI BIOMAP project (Grant Agreement No. 821511). All three registries will provide data and samples to BIOMAP project. These samples will be used to screen for transcriptomic and proteomic biomarkers associated with disease, disease progression and response to therapies. The samples from TREATGermany, which is already running since several years, will be used for identification of potential biomarkers, while the samples from A*Star and BIOMAD NL will serve confirmation purposes.

Doel van het onderzoek

The precise mechanisms driving onset and course are insufficiently understood, disease progression from a current patient state and/or the development of comorbidities are unpredictable, and the optimal type and time-point for intervention is as yet unknown. Understanding relevant subtypes and lifetime trajectories of atopic dermatitis and their molecular underpinnings may enable intervention to prevent comorbidities, and may also make earlier use of therapies and/or use in moderate disease more cost-effective.

Onderzoeksopzet

Baseline, 4 weeks, 3 months, 6 months, 12 months

Onderzoeksproduct en/of interventie

Collection of blood, skin biopsies, tape strips

Contactpersonen

Publiek

Amsterdam UMC
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patient has a diagnosis of AD, based on the U.K. working party’s diagnostic criteria;
- Starts with any type of phototherapy (e.g. UVB) or systemic immunomodulating therapy (e.g. ciclosporin, systemic glucocorticosteroids, azathioprine, methotrexate, mycophenolic acid, dupilumab);
- Has voluntarily signed and dated an informed consent prior to any study related procedure or has a legal representative to do so and is willing to comply with the requirements of this study protocol.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patient uses only (systemic) antibiotics or antihistamines;
- Patient starts with systemic immunomodulating therapy for another indication than atopic dermatitis;
- Insufficient understanding of the study by the patient or parent/legal representative;
- Patient does not participate in the TREAT NL (TREatment of ATopic eczema, the Netherlands) registry.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2020
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	27-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48036
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8323
CCMO	NL69586.018.19
OMON	NL-OMON48036

Resultaten