

# BIOMAD NL study

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<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON21253

### Source

Nationaal Trial Register

### Brief title

BIOMAD NL

### Health condition

Atopic dermatitis, atopic eczema

## Sponsors and support

**Primary sponsor:** Amsterdam UMC, Academic Medical Center

**Source(s) of monetary or material Support:** Innovative Medicines Initiative (IMI)

## Intervention

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

## **Secondary outcome**

-

## **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). 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.

### **Study objective**

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.

### **Study design**

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

### **Intervention**

Collection of blood, skin biopsies, tape strips

## Contacts

### **Public**

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### **Scientific**

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## Eligibility criteria

### **Inclusion criteria**

- 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.

### **Exclusion criteria**

- 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.

## Study design

## Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
<b>Control:</b>	N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-02-2020
Enrollment:	110
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion	
Date:	27-01-2020
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 48036  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

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

## Study results