

# Validation and refinement of the Millennium Criteria for Atopic Dermatitis in a hospital based setting

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To compare the MC with the UK working party diagnostic criteria (UKC) and clinical diagnosis and to refine the MC into a more convenient and reliable set of criteria.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Allergic conditions
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON32432

### Source

ToetsingOnline

### Brief title

Validation and refinement of the millennium criteria

### Condition

- Allergic conditions

### Synonym

allergic eczema, Atopic Eczema

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Atopic dermatitis, Millennium criteria, refinement, Validation

## Outcome measures

### Primary outcome

Sensitivity and specificity (thus diagnostic accuracy) of the MC and UKC.

### Secondary outcome

Positive and negative predictive value of the MC and UKC

## Study description

### Background summary

During the last decades various lists of diagnostic criteria for atopic dermatitis (AD) have been proposed and partially validated. However, there is discrepancy between the current definition of atopy, and how that is applied in diagnosing AD. In order to comply with the new definition of AD, the millennium criteria (MC) were developed in which presence of allergen specific IgE is a mandatory criterion.

### Study objective

To compare the MC with the UK working party diagnostic criteria (UKC) and clinical diagnosis and to refine the MC into a more convenient and reliable set of criteria.

### Study design

A prospective cohort study, hospital based.

### Study burden and risks

This research requires only one study visit. During this visit of approximately 30-45 minutes the patient will be physically examined (mainly inspection) by two dermatologists and the study investigator, successively. If not previously performed a phadiatop test will be done to test allergen specific IgE. We expect no considerable effects of participating in this study other than the risk associated with drawing blood samples.

## Contacts

### Public

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### Scientific

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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

Included are patients that:

- \* Are consecutive new patients from the outpatient clinic of the AMC
- \* either have the diagnosis of atopic dermatitis (AD) or the diagnosis of AD is considered in the differential diagnosis made by resident or dermatologist.
- \* Understand and are willing to sign the written informed consent

## Exclusion criteria

Patients unwilling to participate

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2008

Enrollment: 200

Type: Anticipated

## Ethics review

Approved WMO

Application type: First submission

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**

No registrations found.

**In other registers**

Register	ID
CCMO	NL24845.018.08