Immunophenotyping of inflammatory cells in Atopic Dermatitis

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To perform a comprehensive analysis of the cellular infiltrate in lesional AD skin, using state of the art immunohistochemical techniques.

Ethical review	Not approved
Status	Will not start
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON38740

Source
ToetsingOnline

Brief title
Immunophenotyping in Atopic Dermatitis

Condition

- Allergic conditions
- Epidermal and dermal conditions

Synonym
Atopic dermatitis, eczema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atopic Dermatitis, Atopy Patch Test, Immunophenotyping, Psoriasis

Outcome measures

Primary outcome

We will study the number of skin infiltrating cells per square millimetre skin

in lesional AD skin, non-lesional AD skin, lesional psoriasis skin,

non-lesional psoriasis skin and skin after atopy patch testing. This includes

the analysis of:

- T cells

- B cells

- NK cells

- Dendritic cells

- Eosinophils

- Macrophages

- Mast cells

- Basophils

- Neutrophils

Secondary outcome

Not applicable

Study description

Background summary

Atopic dermatitis (AD) is a pruritic skin disease that is histologically characterised by spongiosis (epidermal intercellular edema) and epidermal

thickening. The skin is infiltrated by a large variety of inflammatory cells, including T cells, B cells, NK cells, eosinophils, mast cells, macrophages, dendritic cells, basophils and neutrophils.2 Although a lot of research has been conducted to understand the pathophysiology of atopic dermatitis, the exact mechanism remains unknown. To understand the pathogenesis of AD, it is essential to exactly know which immune cells are present in AD skin.

Study objective

To perform a comprehensive analysis of the cellular infiltrate in lesional AD skin, using state of the art immunohistochemical techniques.

Study design

Observational study:
4 millimeter skin biopsies will be taken from three different groups:
- lesional versus non lesional skin biopsies will be taken from AD patients (2 biopsies per patient)
- lesional versus non-lesional skin will be taken from psoriasis patients (2 biopsies per patient)
- nonlesional versus atopy patch tested skin in AD patients (3 biopsies per patient)

Study burden and risks

Performing a biopsy entails a slight risk of haemorrhage and infection. A small scar at the site of biopsy will gradually fade in color. An APT will induce erythema and pruritus with sometimes papules and/or vesicles. This reaction gradually disappears after 72-96 hours.
The aim of this study is to investigate the presence of the different types of infiltrating immune cells in lesional AD skin. This will gain more insight in the pathogenesis of AD.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. AD group:
- age range 18 to 70 years
- AD according to diagnostic criteria of Hanifin and Rajka
- patients for APT: sensitised to aeroallergens (previously shown to have a positive APT)
2. Psoriasis group
- chronic plaque psoriasis patients, ages 18-70 years

Exclusion criteria

- topical treatment of the biopsy region with corticosteroids or tacrolimus in the two weeks prior to taking the biopsies
- treatment with systemic corticosteroids or other immunosuppressive medication in the four weeks prior to taking the biopsies
- exposure of biopsy location to (extraordinary) UV sunlight (e.g. UV-therapy, sunny holiday) in in the two weeks prior to taking the biopsies

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	0
Type:	Anticipated

Ethics review

Not approved

Date:	05-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL43326.041.13