Clinical differences between atopic and atopiform dermatitis

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|------------------------------|---|--|--|--|
| 28/12/2006 | | Protocol | | |
| Registration date 28/12/2006 | Overall study status Completed Condition category | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited | | [] Individual participant data | | |
| 14/01/2021 | Skin and Connective Tissue Diseases | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NL754, NTR765

Study information

Scientific Title

Clinical differences between atopic and atopiform dermatitis

Study objectives

We hypothesise that AtopiForm Dermatitis (AFD) is a separate entity with specific characteristics, which needs recognition in order to be diagnosed and treated appropriately.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethical Committee (Medisch Ethische Commissie) on the 24th August 2005 (ref: MEC05/171).

Study design

Case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Atopic dermatitis , Atopiform dermatitis

Interventions

- 1. Percutaneous skin prick test
- 2. Phadiatop blood test
- 3. SCORing Atopic Dermatitis (SCORAD), Eczema Area and Severity Index (EASI)
- 4. Diagnositic criteria: Hanifin and Rajka, United Kingdom working party's and Millennium criteria
- 5. Medical History
- 6. Quality of life: skindex-29 questionnaire and Short Form health survey (SF-36)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

AFD (without allergen-specific IgE) is a separate entity with different, specific characteristics compared to AD (with allergen-specific IgE).

Secondary outcome measures

Gain more information about the clinical aspects of AFD.

Overall study start date

01/03/2006

Completion date

22/12/2006

Eligibility

Key inclusion criteria

- 1. Written informed consent
- 2. Age: over two years old
- 3. Male and female patients
- 4. Clinical diagnosis of Atopic Dermatitis (AD)
- 5. Cases: former negative or unknown allergen-specific Immunoglobulin E (IgE) levels in blood
- 6. Controls: former positive or unknown allergen-specific IgE levels in blood

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

130

Key exclusion criteria

- 1. Other skin diseases, which interfere the study
- 2. Patients unable to comply with the requirements of the study
- 3. Treatment with systemic corticosteroids or phototherapy within four weeks before performing the skin prick test
- 4. Treatment with oral anti-histamines within 48-hour before performing the skin prick test

Date of first enrolment

01/03/2006

Date of final enrolment

22/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre
Academic Medical Center Amsterdam

Amsterdam Netherlands 1105 AZ

Sponsor information

Organisation

Academic Medical Center (AMC) (The Netherlands)

Sponsor details

Department of Dermatology P.O. Box 22660 Amsterdam Netherlands 1100 DD

Sponsor type

Hospital/treatment centre

Website

http://www.amc.uva.nl/

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/03/2008 | 14/01/2021 | Yes | No |