IMProving Treatment of moderate to severe AtopiC Dermatitis in adults by immune- supportive Diet. A proof-of-concept study

Published: 13-12-2023
Last updated: 02-12-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON56216

Source
ToetsingOnline

Brief title
IMPACDD study

Condition

- Epidermal and dermal conditions

Synonym
atopic dermatits, eczema

Research involving
Human

Sponsors and support

Primary sponsor: OLVG

Source(s) of monetary or material Support: Stichting Fonds Onderzoek Huidziekten; Stichting Wetenschappelijk Onderzoek OLVG

Intervention

Keyword: atopic dermatitis, dietary efficacy, EASI, immune-supportive diet

Outcome measures

Primary outcome

main study outcomes (no primary outcome):

Differences in AD severity (including itch), cytokine production, quality of

life, nutrition intake and use of medication.

Secondary outcome

n.a.

Study description

Background summary

Atopic dermatitis (AD) is a chronic disease characterized by visible skin lesions and intense itching that causes serious disease burden in patients, both mentally and physically. There is no complete cure for AD and therefore management currently focuses on avoidance of triggers (e.g. bathing), skin hydration, and reduction of skin inflammation. The relationship between AD and diet and nutrition is complex and unclear and the evidence is scarce. Elimination diets are rarely significantly effective. However, patients with AD often follow unsupervised elimination diets. An immune-supportive diet may ameliorate AD because of the anti-inflammatory effects of the total diet, direct effects of specific nutrients or food components on innate and adaptive immune cells and the role of nutrition in the gut microbiome and gut permeability.

Study objective

to study, in adults with moderate to severe AD,:
1. the effect of an immune-supportive diet on severity of AD (including itch), cytokine production, quality of life, use of medication and nutritional intake;

2. the dietary compliance and feasibility of the immune-supportive diet.

Study design

: A multicentre non-randomised proof-of-concept study on severity of AD in adult patients who visit the outpatient clinics of the dermatology departments of OLVG or AUMC.

Intervention

Patients will receive written and oral dietary advice by an allergy-specialist dietitian regarding the maintenance of a healthy and individually tailored immune-supportive diet during 4 months (including 1 month run in), supported by sample menus, recipes and product information.

At baseline and at the end of the study, AD severity will be measured by the dermatologist and scored by the patient. Cytokines in the skin will be determined by tape striping, quality of life will be scored. Nutrition intake will be recorded by the patients using 3-day food diaries.
Itch and medication use will be scored on a weekly base. After 4 weeks of run-in diet the patients will score the AD severity to monitor the (placebo) effect of enrolment

Study burden and risks

An immune supportive diet is a healthy diet and does not bring any extra risks for the participants. Participating in this study will yield some burden: extra time for dietary adherence and measurements, extra costs (15% extra) and restricted food choices.
However, patients will be reimbursed for extra costs and the dietician will ensure sufficient tasteful and acceptable alternatives. If effective, disease severity including itch will decrease and may heavily outweigh this burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 18 years or older
- Diagnosed with moderate to severe AD by the dermatologist, EASI score 7.1-72.
- Able to speak and write Dutch.

Exclusion criteria

- Other skin diseases
- Not able to speak or write Dutch fluently;
- Pregnancy;
- Multiple clinical relevant IgE mediated food allergies (> 1 staple food or food group, such as cow*s milk or nuts/peanuts/seeds);
- Avoidance of all dairy or gluten;
- Extensive eliminations due to Pollen Food Syndrome, so that a daily variety of raw fruits and/or vegetables is not feasible;
- Individual patients will not start the dietary intervention just before the time of the year in which the AD is usually worsening.
- Antibiotics shorter than 6 weeks prior to the study;
- Using systemic immune suppressants or biologicals;
- Not willing to stop probiotic and nutrient supplements from 4 and 2 weeks subsequently prior to the start of the study
(except medically prescribed or recommended for age such as vitamin D).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-05-2024
Enrollment:	0
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	13-12-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-07-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL85507.100.23