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Research into the disease burden in patients with atopic eczema

Submission date	Recruitment status	[X] Prospectively registered
08/10/2021	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/10/2021	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2022	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Atopic dermatitis (AD) is a chronic inflammatory skin disease and one of the most common chronic diseases worldwide. In developed countries, the lifetime prevalence can be as high as 15-20%. Despite the availability of data at the European or global level, recent data from the Netherlands regarding the characteristics of the disease and disease burden of atopic dermatitis in adults and adolescents are lacking. In addition, there is little information on the journey of patients throughout the Dutch health care system prior to reaching a specialized dermatology center. Such data are essential to understand the true burden of atopic dermatitis and will be useful to inform healthcare agencies, dermatologists and payers. The patients reaching referral centers are expected to suffer from moderate-to-severe AD, and the burden of disease in these patients has not been explored. There are also no recorded data on the patient journey through the Dutch healthcare system before reaching a specialized center and what is the current standard of care offered to patients. Lack of these data often leads to misconceptions about the true burden of this non-fatal disease, so more data are needed for a better understanding of the disease landscape in the Netherlands, including the demographic and disease characteristics of AD patients, the management of their disease and the associated burden experienced by Dutch patients. This study aims to explain these points focusing on moderate to severe AD patients when they reach out to specialized centers, who are able to provide input on their journey and information to the burden of diseases before being treated in a specialized center.

Who can participate?
Patients aged 12 years older with moderate to severe AD reaching out to referral hospital centers experienced in the management of AD

What does the study involve?
During the first hospital visit, demographic data, information about the disease course in recent years and medication use will be collected. Also, patient-reported outcomes questionnaires will be completed by the patient to track the burden of disease before treatment is started in the hospital.

What are the possible benefits and risks of participating?
This is an observational one-site visit study with no extra interventions. There are no physical or

mental risks of participation that can be linked to this study. There are also no direct benefits of participation, but the data collected coulf improve the quality of care for atopic dermatitis in the near future.

Where is the study run from?
Pfizer (Netherlands)

When is the study starting and how long is it expected to run for?
June 2021 to August 2022

Who is funding the study?
Pfizer (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
B7451077

Study information

Scientific Title

APOLO: AtoPic dermatitis - a crOss sectionaL study on disease characteristics and impact On patients

Acronym
APOLO

Study objectives
Despite the availability of epidemiology data of atopic dermatitis at European or global level, recent data from the Netherlands regarding the characteristics of the disease and disease burden of atopic dermatitis in the adult and adolescent population are lacking. In addition, there is little information on the journey of patients throughout the Dutch health care system prior to reaching a specialized dermatology center. Such data are essential to understand the true burden of atopic dermatitis and will be useful to inform health care agencies, dermatologists and payers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/10/2021, Medical research Ethics Committees United (MEC-U) (p/a St. Antonius Ziekenhuis, Koekoekslaan 1, Postbus 2500, 3430 EM Nieuwegein, Netherlands; +31 (0) 88 320 8787; nwmo@dcrfonline.nl), ref: W21.161

Study design
Multicenter observational on-site visit only

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Atopic dermatitis

Interventions
During the first hospital visit demographic data, information about the disease course in recent years and medication use will be collected. Also, patient-reported outcomes questionnaires will be completed by the patient to track the burden of disease before treatment is started in the hospital.

Intervention Type
Other

Primary outcome measure
All measurements (completion of questionnaires) will be done once only during the first hospital visit:
1. How much skin pain has affected the patient's life over the last week, measured using the Dermatology Life Quality Index (DLQI)
2. For patients under 16 years of age: How much skin pain has affected the patient's life over the last week, measured using the Children Dermatology Life Quality Index (CDLQI)]
3. Health-related quality of life; mobility, self-care, usual activities, pain/discomfort and anxiety /depression measured using EuroQol-5 Dimensions-3 Level scale (EQ-5D-3L)
4, How much having a child with atopic dermatitis affects the quality of life of other (adult) members of the family, measured using the Dermatitis Family Impact (DFI)
5. Symptoms/itch and impact on the domains of work, and sleep disturbance and pain, measured using the Patient Oriented Eczema Measure (POEM), Peak Prutitus Numerical Severity Scale (PP-NRS), Work Productivity and Activity Impairment Questionnaire (WPAI)
6. Sleep disturbance and pain measured using self-reported sleep and pain measurement

Secondary outcome measures
During the first visit the following information of the patient will be collected once only from the patient's medical records (no measurements or interventions are needed):
1. Main characteristics of this patient population (sociodemographic, clinical, including body surface area [BSA], specific areas of interest involved, etc) using descriptive statistics and severity expressed as a percentage of patients with AD of different severity in the selected cohort
2. Drug categories used currently and in the past, in this patient population
3. Main characteristics of healthcare resources utilized, including specialty and frequency of consultation of involved healthcare professionals (HCPs), hospital visits or hospitalizations for AD in last year (unless defined otherwise) using descriptive statistics

Overall study start date
01/06/2021

Completion date
01/08/2022

Eligibility

Key inclusion criteria
1. ≥12 years of age (12-15 and ≥16 years of age)
2. Clinical diagnosis of atopic dermatitis (AD)
3. Severity of AD classified as moderate to severe as per the selected Investigator Global Assessment (IGA) scale (Validated Investigator's Global Assessment (vIGA-AD): vIGA-AD ≥3). Grade 3 is defined as clearly perceptible erythema (dull red), clearly perceptible induration /papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present. [Simpson 2020]
4. Evidence of a personally signed and dated informed consent (assent) document indicating that the patient (or a legally acceptable representative) has been informed of and consented (assented where applicable) to all pertinent aspects of the study. Parents (or a legally acceptable representative) will sign the consent form for patients <18 years of age

5. Seeking medical attention for AD to the clinic for the first time (no previous visit for AD), including:
5.1. New M2S AD patients who present themselves for the first time at the center of reference
5.2. Known M2S AD patients who haven't been in regular follow-up for at least 2 years
5.3. Patient referred within the center who fulfils the above criteria

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Current participation in interventional clinical study
2. Other active concurrent dermatological conditions which may confound correct diagnosis or symptom scores (i.e., psoriasis, chronic urticaria)
3. Children <12 years of age or mild severity of AD as per vIGA-AD (vIGA-AD equal or less than 2, where 2 is mild erythema, and mild papulation/infiltration)

Date of first enrolment
01/12/2021

Date of final enrolment
01/08/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC
Doctor Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Study participating centre
Bravis
Langendijk 75
Breda

Netherlands
4819 EV

Sponsor information

Organisation
Pfizer (Netherlands)

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2909LD
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Sponsor type
Industry

Website
https://www.pfizer.nl

ROR
https://ror.org/02bzf1224

Funder(s)

Funder type
Industry

Funder Name
Pfizer

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The statistical analysis plan is not available yet and the study protocol will be shared at a later date.

Intention to publish date
01/08/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other