EVALUATION OF BIOMARKERS OF ATOPIC DERMATITIS IN PEDIATRIC PATIENTS WHOSE DISEASE IS NOT ADEQUATELY CONTROLLED WITH TOPICAL PRESCRIPTION THERAPIES OR WHEN THOSE THERAPIES ARE NOT MEDICALLY ADVISABLE

Published: 05-08-2019
Last updated: 09-04-2024

To explore associations between biomarkers of atopic dermatitis(AD) and:• Disease state and time course of AD,• Disease state and evolution of selected atopiccomorbid conditions,• Effectiveness of specific AD treatments.

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

Summary

ID

NL-OMON48261

Source
ToetsingOnline

Brief title
PEDISTAD BIOMARKER STUDY

Condition

- Epidermal and dermal conditions

Synonym
atopic dermatitis ; eczema

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis
Source(s) of monetary or material Support: Sanofi-Aventis Groupe

Intervention

Keyword: biomarker, dermatitis, LPS15496, pedistad

Outcome measures

Primary outcome

Biomarkers including genetic and protein data.

Secondary outcome

not applicable

Study description

Background summary

Due to the natural history of AD in infancy and childhood, there is a lot of potential in the
discovery of biomarkers that may allow the identification of individuals at high risk of developing
AD, and once the disease is established, as is the case in the patient population to be enrolled in
this study, the potential lies in the discovery of biomarkers that can predict the course of disease
progression or response to treatment.

This study will focus on the collection and biobanking of biomarker samples which will be
subsequently merged with data from the PEDISTAD registry for the exploratory evaluation of biomarkers and AD disease state, time course, evolution of selected atopic comorbid

conditions, and treatment response of specific systemic therapies.

Study objective

To explore associations between biomarkers of atopic dermatitis (AD) and:
• Disease state and time course of AD,
• Disease state and evolution of selected atopic comorbid conditions,
• Effectiveness of specific AD treatments.

Study design

Prospective, multinational, multicenter, phase IV, biomarker study.
This is a companion study of the OBS15333 pediatric AD registry that will evaluate biomarkers, including genetic (deoxyribonucleic acid [DNA] and/or ribonucleic acid [RNA]) and protein markers, patient*s characteristics and disease characteristics in AD disease state and time-course, and treatment response of specific systemic AD therapies.

Intervention

Blood samples for protein and RNA biomarker analyses will be taken at baseline, annually during study participation, at the end of the study, and prior to initiating or switching of systemic AD therapy. Blood volume required is in accordance with guidance from regulatory authority and expert recommendations.

Cheek swabs for DNA biomarker analysis will be taken at baseline, but may be taken at any subsequent visit, if not performed at baseline.

Study burden and risks

Taking a blood sample may cause discomfort, bruising and very rarely infection at the site where the skin is punctured by the needle. There is a rare risk of nerve injury during collection of the blood sample. The subject may also experience dizziness, nausea or fainting during blood taking.

When a cheek swab is taken, the subject's cheek may feel a bit raw.

There is a low risk of loss of confidentiality of the subject's personal information; however, steps have been taken to help ensure this will not

happen.

Contacts

Public
Sanofi-aventis

Avenue Pierre Brossolette 1
Chilly-Mazarin Cedex 91385
FR
Scientific
Sanofi-aventis

Avenue Pierre Brossolette 1
Chilly-Mazarin Cedex 91385
FR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Participation in the OBS15333 pediatric AD registry
2. Signed informed consent by the parent/legally acceptable representative and assent by the participant appropriate to the participant*s age.

Exclusion criteria

Not applicable

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2019
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2019
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	04-09-2023
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
ClinicalTrials.gov	NCT03849716
CCMO	NL69478.099.19