An Immuno-Dermatological disease registry to understand the burden of Atopic dermatitis (AD), Alopecia areata (AA), and Vitiligo in Indian Patients

First published: 17/04/2023

Last updated: 19/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS48566

Study ID

106116

DARWIN EU® study

No

Study countries

India

Study description

A prospective observational multi-center study in India to evaluate the epidemiological burden of mild, moderate and severe atopic dermatitis, vitiligo and alopecia areata.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

- DY Patil Hospital
- Father Muller Medical College Hospital
- Wizderm Specialty Skin and Hair Clinic
- Vibrance Skin Clinic
- Indushree Skin Clinic
- Lokmanya Tilak Municipal General Hospital and Lokmanya Tilak Municipal Medical College

- Bharati Vidyapeeth (deemed to be University) Medical College Hospital & Research Centre
- KPC Medical College and Hospital
- Ayana Clinic
- B. J. Medical College & Civil Hospital
- Venkateshwar Hospital
- Dermaworld Skin Clinic
- Dr. D.Y.Patil Medical College, Hospital and Research
- Maharishi Markandeshwar Institute of Medical sciences and Research
- Indus International Hospital
- Anisha Private Clinic

Networks

- Insignia

Contact details

Study institution contact

Sreenath Hariharan Sreenath.Hariharan@pfizer.com

Study contact

Sreenath.Hariharan@pfizer.com

Primary lead investigator

Lavinia Popa

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/05/2022

Actual: 28/06/2022

Study start date

Planned: 29/09/2023

Actual: 28/08/2023

Date of interim report, if expected

Planned: 31/01/2026

Date of final study report

Planned: 30/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B7451103 Non-Interventional Study Protocol Version 1.0_ 30 September 2022_Redacted.pdf (3.71 MB)

B7451103_NIS Protocol v3.0_Amendment 2 Clean Copy_23DEC2024_Redacted.pdf (4.07 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

The objective of this study is to evaluate the epidemiological burden of mild, moderate and severe atopic dermatitis, vitiligo, and alopecia areata across enrolled dermatology centers.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Other

Non-interventional study design, other

Prospective longitudinal study

Study drug and medical condition

Medical condition to be studied

Dermatitis atopic

Alopecia areata

Vitiligo

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

3000

Study design details

Outcomes

To evaluate the epidemiological burden of mild, moderate and severe atopic dermatitis, vitiligo and alopecia areata in patients across dermatology centers in India.

Explain the current diagnostic criteria and grading modalities for AD, vitiligo and AA, to understand the burden of disease with a demographic overview Better understand the treatment for the diseases: topical, advanced therapies, surgical interventions and cosmetic procedures, the Unmet needs in diagnosis and management of dermatological disorders. Focus on patients’ perspectives on benefits.

Data analysis plan

Descriptive statistics will be presented to describe patient characteristics. Categorical covariates will be described by frequency distribution while continuous covariates expressed in terms of their mean and standard deviation or median and interquartile range (IQR) as appropriate.
The bivariate analysis will be conducted to determine if there is any association between the outcome and the exposure (the covariates).
Unadjusted comparisons between groups of covariates and outcomes will be evaluated using appropriate tests: Pearson's chi-square test will used for dichotomous categorical variables, t-test will be used for continuous variables, and the Mann-Whitney U test for non-parametric variables, p-values will be generated and 5% level of significance will be considered.
In case of multiple testing or stepdown procedure either Tukey HSD or Bonferroni adjustment to p-value will be applied.

Documents

Study, other information

B7451103 Non Interventional Study Protocol Abstract V2.0_19 April 2023_Redacted.pdf (719.94 KB)
B7451103 Protocol Abstract 30 September 2022_Redacted.pdf (1.89 MB)
B7451103_NIS Protocol Abstract V3.0_Clean Copy_23DEC2024_Redacted.pdf (732.41 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No