Spanish Registry of Atopic Dermatitis (BIOBADATOP)

First published: 14/08/2024

Last updated: 14/08/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS25364

Study ID

31712

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Registries have shown to be an important pharmacovigilance strategy, as they provide data on non-selected populations, with long periods of follow-up and with comparison groups that allow for the calculation of meaningful risks.

Previous experiences in psoriasis, including Biobadaderm (the Spanish Registry of Adverse Events Associated with Biologic Drugs in Dermatology) and Psonet (European Network of Psoriasis Registries), have shown the importance of establishing specific registers of patients treated with systemic therapies to describe long term safety of therapy.As happened with psoriasis, over the last years, new immunomodulatory drugs are been developed for the treatment of adults with moderate-to-severe atopic dermatitis (AD). They all affect specific immune pathways and raise safety concerns related to all immunomodulatory drugs. Dupilumab is the first biologic that has been approved by the FDA and the EMA, for the treatment of adults with AD. We expect new drugs for AD to reach the market in the next decade, leading to an increased use of dupilumab and the progressive addition of new molecules. Considering that the prevalence of AD is high in the population and the severe impairment in the quality of life of the patients, there are many potential users. For this reason, knowing their side effects in real life use in the shortest period of time is an important public health objective. Many other outcomes can be relevant in an AD registry, including effectiveness outcomes. We will take advantage of the previous work done by the “Harmonising Outcome Measures for Eczema”(HOME) initiative, that has studied and described the validity of outcome measures in atopic dermatitis.The Spanish Registry of Systemic therapy in atopic eczema, BIOBADATOP, assesses drug safety and treatment effectiveness as well as treatment impact on quality of life in children and adults with atopic eczema receiving systemic immuno-modulatory therapies in Spanish daily practice.

Study status

Ongoing

Research institutions and networks

Institutions

Unidad de Investigación, Fundación Piel Sana (FPS)

Spain

First published: 24/10/2017

Last updated: 14/08/2024

Institution | Not-for-profit | ENCePP partner

Hospital Universitario de Gran Canaria Doctor Negrín Las Palmas, Gran Canaria, Spain, Hospital de la Princesa Madrid, Spain, Hospital del Mar Barcelona, Spain, Hospital Miguel Servet Zaragoza, Spain, Hospital Santa Creu i Sant Pau Barcelona, Spain

Networks

European TREatment of ATopic eczema registry Taskforce (TREAT) (European TREAT Registry Taskforce)

Denmark

France

Germany

- [ ] Italy
- [ ] Netherlands
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

First published: 12/10/2018

Last updated: 20/08/2024

Network

Contact details

Study institution contact

Ignacio García-Doval ignacio.garcia.doval@aedv.es

Study contact

ignacio.garcia.doval@aedv.es

Primary lead investigator

Ignacio García-Doval

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/0001

Study start date
Planned: 10/12/2018

Actual: 01/01/2020

Date of final study report
Planned: 01/01/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Own, Sanofi, Pfizer, Abbvie, Almirall.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Link to study webpage.

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study topic, other:

Atopic dermatitis

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Inception cohort of patients receiving systemic therapy for atopic dermatitis.

Main study objective:

The main objectives are:1. To assess short and long-term safety of systemic therapies (including phototherapy) for atopic eczema (pharmacovigilance).2. To assess short and long-term effectiveness of systemic therapies, providing a basis for shared decision making and guidelines.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ADTRALZA

CIBINQO

DUPIXENT

OLUMIANT

RINVOQ

Medicinal product name, other

methotrexate, cyclosporine, azathioprine

Anatomical Therapeutic Chemical (ATC) code

(D11AH05) dupilumab

dupilumab

(L04A) IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Medical condition to be studied

Dermatitis atopic

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

Estimated number of subjects

2000

Study design details

Setting

Dermatology departments in Spain.

Outcomes

Treatment safety (pharmacovigilance): we will still be able to conduct a meaningful descriptive analysis of more common AEs and SAEs collected over an at least one-year period for each treatment modality.Treatment effectiveness: Effectiveness of the study medications will be assessed using objective measures (EASI) and patient-reported outcomes (POEMS).

Data analysis plan

The initial analyses will consist of comparisons in baseline status between the individuals in the treatment cohorts. For the purposes of analysis follow-up time will be start with enter in the cohort or first dose of a drug and will end at the earliest of the following: exiting the register, loss to follow-up, enter in a clinical trial, death or end of study period. Incidence rates for patients initiating new treatments and initiating other conventional systemic therapies will be estimated crude and stratified by confounding factors. Then time-dependent regression analyses will be undertaken to compare event rates between groups, using standard multivariable analyses to reduce confounding. We will use other statistical techniques, including propensity score matching, to accommodate confounding by indication. As children and adolescents may have a different phenotype of AE compared to adults and may respond differently to systemic

therapy, we will explore this by stratifying groups.

Documents

Study publications

https://aedv.es/investigacion-registro-espanol-dermatitis-atopica-publicaciones/

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

DoIForm_v1.6_YGC.pdf (1.52 MB)

Composition of steering group and observers

EUPAS25364_steering group.pdf (278.36 KB)

Signed code of conduct

empty-file.pdf (14.94 KB)

Signed code of conduct checklist

empty-file.pdf (14.94 KB)

Signed checklist for study protocols

empty-file.pdf (14.94 KB)

Data sources

Data sources (types)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

No

CDM Mappings

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No