Spanish Registry of Systemic Treatments in Psoriasis (Biobadaderm)

First published: 05/10/2014

Last updated: 06/08/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS7607

Study ID

7608

DARWIN EU® study

No

Study countries

Spain

Study description

BIOBADADERM is a prospective cohort of patients receiving biologic drugs that can be compared with another cohort of patients receiving other systemic treatments. One of the cohorts is made up of all consecutive psoriasis patients

who begin any biological therapy (including infliximab (INF), etanercept (ET), efalizumab (EFA), adalimumab (ADA), rituximab (RTX) and ustekinumab (UTK)) in each centre. The control cohort consists of psoriasis patients who begin, for the first time, a nonbiologic systemic treatment (methotrexate, cyclosporine or acitretin).The objectives of BIOBADADERM are:Identify adverse events (AEs) occurring during the relevant treatment with biologic therapies, and estimate their frequency,identify unexpected AEs, particularly those that may occur after long periods of exposure, identify relevant AEs that arise after discontinuation of treatment,estimate the relative risk of developing AEs with biologic therapies in patients with psoriasis compared to psoriatic patients exposed to other systemic (non-biological), andIdentify risk factors for AEs in patients with these treatments.The database includes demographic, diagnostic and comorbidity data, the treatments performed, the duration of these treatments and the adverse effects that arise (coded using MedDRA).The included data are continually revised online by a study monitor to verify consistency, comprehensiveness, and absence of anomalies. A follow-up visit is made every year during which a sample of the the data in the database are compared with those in the clinical records.

Study status

Ongoing

Research institutions and networks

Institutions

Fundación Academia Española de Dermatologia y Venereología

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Research Unit

Parc de Salut Mar Barcelona (PSMAR)

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Hospital Universitario 12 de Octubre

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Hospital General Universitario de Alicante (ISABIAL)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Research Unit. Fundación AEDV Madrid, Spain, Hospital Universitario de la Princesa Madrid, Spain, Hospital Universitario de Gran Canaria Dr Negrín Las Palmas, Spain, Hospital Universitari German Trias y Pujol. Badalona, Barcelona, Spain, Hospital Universitario 12 de Octubre Madrid, Spain, Hospital Clinic Barcelona, Spain, Fundación Hospital Alcorcón Alcorcón, Madrid, Spain, Hospital Universitario Reina Sofía Córdoba, Spain, Hospital del Mar. IMAS Barcelona, Spain, Hospital General Universitario de Alicante Alicante, Spain

Networks

European Registry of Psoriasis (Psonet)

Austria

Czechia

Denmark
France
Germany
Italy
Lithuania
Netherlands
Portugal
Romania
Slovenia
Spain
Sweden
Switzerland
United Kingdom

First published: 08/08/2018

Last updated: 20/08/2024

Network

Contact details

Study institution contact

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Study contact

investigacion@aedv.es

Primary lead investigator

Ignacio Garcia-Doval

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/06/2008

Study start date
Actual: 01/10/2008

Data analysis start date
Actual: 01/12/2009

Date of interim report, if expected
Planned: 01/10/2015

Date of final study report
Planned: 01/12/2020

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Abbvie, Janssen, MSD, Novartis, Pfizer, Agencia Española del Medicamento y Productos Sanitarios (AEMPS)

Study protocol

5 Protocolo Biobadaderm V7.1-2011.pdf (381.38 KB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To describe safety of systemic drugs used in psoriasis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(D05BB02) acitretin

acitretin

(L04AB) Tumor necrosis factor alpha (TNF-alpha) inhibitors

Tumor necrosis factor alpha (TNF-alpha) inhibitors

(L04AC05) ustekinumab

ustekinumab

(L04AD01) ciclosporin

ciclosporin

(L04AX03) methotrexate

methotrexate

Medical condition to be studied

Psoriasis

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

3.000

Study design details

Outcomes

Serious Adverse Events Time Frame: an expected mean follow-up of 5 years , Other adverse events leading to changes in drug therapy or unexpected visits to health provider Time Frame: an expected mean follow-up of 5 years

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Data analysis plan

Analysis consists of description of rates, rate ratios and adjusted rate ratios (adjusted for possible confounders, age always included).

Documents

Study publications

Garcia-Doval I, Carretero G, Vanaclocha F, Ferrandiz C, Daudén E, Sánchez-Caraz...

Sánchez-Moya, A.I., García-Doval, I., Carretero, G., Sánchez-Carazo, J., Ferran...

Carrascosa JM, Vilavella M, Garcia-Doval I, Carretero G, Vanaclocha F, Daudén E...

Carretero G, Ferrandiz C, Dauden E, Vanaclocha Sebastian F, Gómez-García FJ, He...

Medina C, Carretero G, Ferrandiz C, Dauden E, Vanaclocha F, Gómez-García FJ, He...

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)

Disease registry

Other

Data sources (types), other

Exposure registry

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