# 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**

Ignacio Garcia-Doval investigacion@aedv.es

Study contact

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**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

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

Not applicable

# Methodological aspects

# Study type

# Study type list

**Study type:**

Non-interventional study

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**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

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**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**

3000

## 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

**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...

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# 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

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**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