Spanish Registry of Systemic Treatments in Psoriasis (Biobadaderm)

First published: 05/10/2014

Last updated: 06/08/2024





Administrative details

EU PAS number	
EUPAS7607	
Shorder ID	
Study ID	
7608	
DARWIN EU® study	
No	
Charles a constant of	
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), and Identify 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)

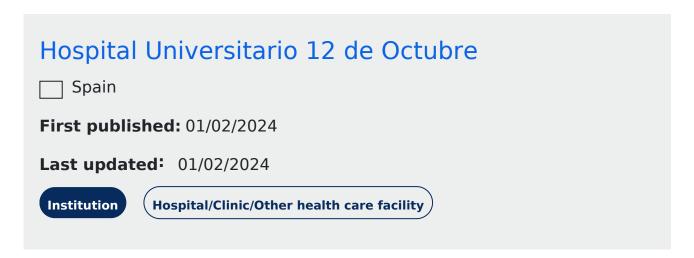
Spain

First published: 01/02/2024

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Institution

Hospital/Clinic/Other health care facility



Hospital General Universitario de Alicante (ISABIAL)

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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

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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

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

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...

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

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No