Spanish Registry of Systemic Treatments in Psoriasis (Biobadaderm)

First published: 05/10/2014
Last updated: 05/10/2014

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/7608

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 institution and networks

Institutions

Fundación Academia Española de Dermatologia y Venereología
First published: 01/02/2024
Last updated 01/02/2024
Institution

Research Unit

Hospital Universitario 12 de Octubre
Spain
First published: 01/02/2024
Last updated 01/02/2024
Institution
Hospital/Clinic/Other health care facility

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 General Universitario de Alicante (ISABIAL)

First published: 01/02/2024
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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
~~08/08/2018~~
Network ENCePP partner

Contact details

Study institution contact
Ignacio Garcia-Doval
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

- Pharmaceutical company and other private sector
- Other

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

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
100000095363
acitretin
100000096879
ciclosporin
100000096884
methotrexate
100000096864
Tumor necrosis factor alpha (TNF-alpha) inhibitors
100000096875
ustekinumab

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
Renal impaired
Hepatic impaired
Immunocompromised
Pregnant women

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

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