

# Patient's perspective: emotional impact of the COVID-19 pandemic in psoriasis patients treated with biological drugs and small molecules in real clinical practice

**First published:** 08/06/2020

**Last updated:** 21/07/2020

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/36445>

### EU PAS number

EUPAS35712

### Study ID

36445

### DARWIN EU® study

No

## Study countries

☐ Spain

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## Study description

The current COVID-19 pandemic may have had an impact not only on patients' health, but also on their social behaviour and their perception of vulnerability resulting from exposure to immunosuppressive/immunomodulatory psoriatic drugs. We sought to clarify the status of these patients with respect to possible COVID-19 involvement and to detect changes in their treatment regimen, the reason why they made them as well as the influence in their social behaviour. We conducted a retrospective study and included 174 patient under biologics or small molecules during the onset and the development of the crisis. We found a not significant incidence of COVID-19 infection and we bring to light emotional impact of pandemic in this group of patients, as an increased worry about their immunosuppressed status has been evidenced. Individuals also took additional measures to protect themselves and looked for information on internet. COVID-19 pandemic has not only had an impact on health, but also on the emotional sphere of psoriatic patients.

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## Study status

Finalised

# Research institutions and networks

## Institutions

[Hospital Universitario Príncipe de Asturias](#)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

## Contact details

### Study institution contact

Ana Rodríguez-Villa Lario

Study contact

[anarvlario@gmail.com](mailto:anarvlario@gmail.com)

### Primary lead investigator

Ana Rodríguez-Villa Lario

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 02/03/2020

Actual: 02/03/2020

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### Study start date

Planned: 09/03/2020

Actual: 09/03/2020

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### Date of final study report

Planned: 08/06/2020

Actual: 08/06/2020

## Sources of funding

- Pharmaceutical company and other private sector
- Non-for-profit organisation (e.g. charity)
- EU institutional research programme
- Other

## More details on funding

Name of Pharmaceutical companies, Charities, Government body, Research councils, EU funding scheme, Other: not provided

## 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 topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

We sought to clarify the status of patients on immunosuppressive or immunomodulator drugs with respect to possible COVID-19 involvement and to detect changes in their treatment regimen, the reason why they made them as well as the influence in their social behaviour.

## Study Design

**Non-interventional study design**

Cross-sectional

Other

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**Non-interventional study design, other**

Retrospective study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L04AC13) ixekizumab

ixekizumab

(L04AC13) ixekizumab

ixekizumab

(L04AC10) secukinumab

secukinumab

(L04AA32) apremilast

apremilast

(L04AB04) adalimumab

adalimumab

(L04AC16) guselkumab

guselkumab

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**Medical condition to be studied**

Psoriasis

## Population studied

**Short description of the study population**

Psoriasis patients under treatment in our Hospital during the last year. Inclusion criteria were psoriasis being under biologics or small molecules during the onset and the development of the crisis, verbal consent and adulthood. Exclusion criteria included impossibility of telephone contact or refusal to participate.

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**Age groups**

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)

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### **Special population of interest**

Immunocompromised

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### **Estimated number of subjects**

174

## Study design details

### **Data analysis plan**

A statistical analysis was performed with chi-squared, Fisher exact tests and Student's t-test using Statistical Package for Social Sciences (SPSS®) for Windows, version 25.0 (Armonk, NY: IBM Corp).

## Documents

### **Study results**

[Patient s perspective psychological burden of the COVID 19 pandemic in 146 psoriatic patients treated with biological drugs and small molecules in.pdf\(1.17 MB\)](#)

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### **Study publications**

[Rodríguez-Villa Lario A, Vega-Díez D, González-Cañete M, et al. Patient´s persp...](#)

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## Data management

## Data sources

## **Data sources (types)**

Drug dispensing/prescription data

Patient surveys

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No