# Observational study to evaluate the potential effects of biological, biosimilar, and targeted synthetic disease-modifying antirheumatic drugs in the appearance of symptoms compatible with COVID-19 infection (PreCOVIDMar)

**First published:** 19/04/2020

**Last updated:** 20/04/2020

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS34806

**Study ID**

34824

**DARWIN EU® study**

No

**Study countries**

Spain

**Study description**

This is an observational, retrospective study to determine the cumulative incidence of symptoms compatible with COVID19 infection in patients receiving biological, biosimilar or targeted synthetic disease-modifying antirheumatic drugs (bDMARDs, bsDMARDs, tsDMARDs), when compared with patients suffering from other rheumatic diseases not treated with these drugs. The study also aims to investigate whether there is any immunosuppressive/ immunomodulatory treatment that has a protective effect against symptoms compatible with coronavirus infection.All patients diagnosed with any immune-mediated inflammatory disease (IMID) and actually receiving bDMARDs, bsDMARDs or tsDMARD managed as outpatients in the hospital pharmacy department will be recruited from 14 selected primary care centers in Barcelona (Spain). Additionally, patients attending from September 2019 to March 2020 the Hospital del Mar Rheumatology Department (Barcelona, Spain) and not being treated with these immunomodulatory drugs will also be included. A medical history revision of included patients will be performed, focusing mainly on patient’s comorbidities, current treatments followed and COVID signs and symptoms. Regarding the COVID infection, the following variables were recorded: COVID diagnostic test result, hospitalization due to COVID infection, and presence of COVID symptoms. Last variable was defined as any physical or telephonic contact informing about symptoms compatible with COVID-19 infection, both to the hospital or to the primary care center, from the 1st to the 29th of March.Poisson regression models with robust variance estimation will be used to estimate incidence rate ratios (IRR) and 95% confidence intervals. Models will be adjusted by sex, age and comorbidities.

**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Parc de Salut Mar Barcelona (PSMAR)

Spain

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

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Institution | Hospital/Clinic/Other health care facility

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Jordi Monfort

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 16/04/2020

Actual: 16/04/2020

**Study start date**
Planned: 20/04/2020

Actual: 16/04/2020

**Date of final study report**
Planned: 01/05/2020

## Sources of funding

- Other

## More details on funding

IMIM

## Study protocol

CLINICAL RESEARCH PROTOCOL_PreCOVIDMAR_Eng.pdf(197.17 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

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Main study objective:**

To study the cumulative incidence of symptoms compatible with coronavirus infection in patients treated with bDMARDs, bsDMARDs, and tsDMARDs compared with a similar population of patients not treated with DMARDs.

## Study Design

**Non-interventional study design**

Cohort

## Population studied

**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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**Estimated number of subjects**

2551

## Study design details

**Outcomes**

Treatment with bDMARDs, bsDMARDs, or tsDMARDs and consultation for symptoms of COVID infection. The patient will be considered to be in treatment when this is stated in his/her updated hospital prescription and regularly picks the treatment from the pharmacy. Other immunosuppressive /immunomodulatory treatment with a protective effect on symptoms compatible with coronavirus infection

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**Data analysis plan**

Poisson regression models with robust variance estimation will be used to estimate incidence rate ratios (IRR) and 95% confidence intervals. Models will be adjusted by sex, age and comorbidities

# 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)**

Drug dispensing/prescription data

Electronic healthcare records (EHR)

## 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