

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)

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Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/34824>

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 institution and networks

Institutions

Parc de Salut Mar Barcelona (PSMAR)

Spain

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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

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)

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

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

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