# Pharmacogenetic study to predict the response to Tocilizumab in patients infected with SARS-CoV-2 (COVID-19)

**First published:** 09/04/2020

**Last updated:** 10/03/2021

Study Planned

## Administrative details

**EU PAS number**

EUPAS34653

**Study ID**

39819

**DARWIN EU® study**

No

**Study countries**

Spain

**Study description**

This study aims to provide an accurate tool that allows patients to be classified "a priori" according to their probability of success in responding to one of the immunosuppressive biological drugs that are currently being administered to combat SARS-CoV-2 infection, Tocilizumab. Tocilizumab is an interleukin-6 (IL-6) cell receptor blocker, which has been shown to be effective in fighting SARS-CoV-2 infection in different pre-clinical studies and is currently indicated for prescription in patients with a moderate level of severity of lung involvement. Likewise, different cynical trials have been initiated, in China (ChiCTR2000029765) and Italy, in patients with pneumonia and early respiratory failure (Favalli et al. 2020, PMID: 32205186).With the recent SARS-CoV-2 pandemic, different lines of research have shown that, more than the virus itself, what really aggravates the situation of infected patients, is the "cytokine storm" (Prompetchara et al. 2020, PMID: 32105090). This phenomenon, which can lead to the onset of viral sepsis, inflammation-induced lung damage, and even death, it results from dysregulation of the patient's immune system when trying to fight the virus. This "cytokine storm" is made up of very high levels of proinflammatory cytokines such as Interleukin-1β (IL-1β), IL-2, IL-6, IL-7, IL-8, tumor necrosis factor-α ( TNF-α) and chemokines such as CXCL10 or CCL2 among others, together with a significant degree of lymphopenia and a drastic decrease in Interferon (IFN) (Favalli et al. 2020, PMID: 32205186). Specifically, the increase in IL-6 associated with severe pneumonia can have deleterious effects on the adaptive immune response (sarzi-Puttini et al. 2020, PMID: 32202240).

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**Study status**

Planned

# Research institutions and networks

## Institutions

# University Hospital of A Coruña (CHUAC)

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Institution

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Ignacio Rego Pérez

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 24/04/2020

### Study start date

Planned: 27/04/2020

### Data analysis start date

Planned: 27/08/2020

**Date of interim report, if expected**
Planned: 28/09/2020

**Date of final study report**
Planned: 27/10/2020

## Sources of funding

- Other

## More details on funding

ISCIII

## 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:**

Drug utilisation

**Main study objective:**

Identify a biomarker panel of genetic variants that allows to predict the response to Tocilizumab

## Study Design

**Non-interventional study design**

Other

**Non-interventional study design, other**

Drug interaction study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L04AC07) tocilizumab

tocilizumab

**Medical condition to be studied**

Pneumonia viral

**Additional medical condition(s)**

SARS-CoV-2 infection

## 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)

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**Estimated number of subjects**

384

## Study design details

**Data analysis plan**

Different bioinformatics tools will be used to develop a working "pipeline" thatFirst, allow the quality processing and analysis of the sequences obtained, followed byalignment against a reference sequence to finally identify the variants. Then the appropriate statistical analyzes will be carried out to identify variantsdifferential genetics between drug response groups using severe algorithms ofcorrection for multiple comparisons, Benjamini-Hochberg type.

## 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)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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