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

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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).

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)

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