

# COVID-19 IN PATIENTS WITH HEART FAILURE AND INHERITED CARDIAC CONDITIONS (C19-ICC)

**First published:** 21/04/2020

**Last updated:** 08/05/2020

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS34756

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### Study ID

35231

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### DARWIN EU® study

No


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### Study countries

 Argentina

 Brazil

 Greece

 Ireland



Israel



Italy



Netherlands



Spain



United Kingdom



United States

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## **Study description**

Patients with heart diseases are a group at risk of developing complications associated with Covid-19 disease. The available information on the evolution, complications, responses to different treatments of patients with inherited heart diseases is extremely scarce. Certain commonly used drugs for these conditions may have an impact on the clinical course of the infection (ACE inhibitors or ARBs). Some antiviral drugs used in the treatment of Covid-19 alter the QT interval and facilitate the onset of arrhythmias. Direct infection of Covid-19 in the myocardium has been reported. The main objective is to describe the clinical course of Covid-19 infection in patients previously diagnosed with an inherited cardiac condition. The secondary objectives are: (1) to assess the relation between previous chronic treatment with ACE inhibitors and ARBs and the severity of Covid-19 infection, and (2) to assess the impact of established antiviral treatments on cardiac disease (heart function, ECG changes, arrhythmias and cardiac complications). Methods: The inclusion criteria are: patients with confirmed Covid-19 infection previously diagnosed with any of the following inherited cardiac diseases: hypertrophic cardiomyopathy, dilated cardiomyopathy, restrictive cardiomyopathy, arrhythmogenic cardiomyopathy, non-compaction cardiomyopathy, long or short QT syndrome, Brugada syndrome or catecholaminergic polymorphic ventricular tachycardia. Participants have to provide informed consent. The project has the approval of the ethics committee of Virgen de la Arrixaca Clinical University Hospital. Data will be collected in a completely anonymous manner

prospectively and retrospectively. Participation in the registry does not mean a different diagnosis process or clinical treatment. A specific online database (e-CRF) is available in compliance with all the international data protection regulations and the Spanish and European regulations. This is international registry (EU,UK,America)

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

[Hospital Clínico Universitario Virgen de la Arrixaca](#)

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**Institution**

### Networks

[CIBERCV](#)

## Contact details

### **Study institution contact**

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Study contact

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**Primary lead investigator**

Juan R Gimeno Blanes

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 03/04/2020

Actual: 01/05/2020

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**Study start date**

Planned: 03/04/2020

Actual: 16/04/2020

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**Data analysis start date**

Planned: 20/04/2020

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**Date of interim report, if expected**

Planned: 11/05/2020

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**Date of final study report**

Planned: 12/04/2021

## Sources of funding

- Other

## More details on funding

ISCIII (Spain)

## 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 type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

#### **Main study objective:**

The main objective is to describe the clinical course of Covid-19 infection in patients previously diagnosed with (1) an inherited cardiac condition and/or (2) prior diagnosis of heart failure.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medical condition to be studied**

Hypertrophic cardiomyopathy

Cardiomyopathy

Brugada syndrome

Long QT syndrome

Arrhythmogenic right ventricular dysplasia

Cardiac failure

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### **Additional medical condition(s)**

Confirmed Covid-19 infection previously diagnosed with: hypertrophic cardiomyopathy, dilated cardiomyopathy, restrictive cardiomyopathy, arrhythmogenic cardiomyopathy, non-compaction cardiomyopathy, long or short QT syndrome, Brugada syndrome or catecholaminergic polymorphic ventricular tachycardia. (All centres) Additionally patients with prior diagnosis of heart failure (for Spanish & Argentina)

## 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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## **Special population of interest**

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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## **Estimated number of subjects**

1000

# Study design details

## **Outcomes**

The main grouping and comparison variables established for the main objective are variables regarding infection severity (need of hospitalisation, admission to ICU) and regarding complications (Covid-19-related mortality or heart-disease-related mortality). Impact of established antiviral treatments on cardiac disease (heart function, ECG changes, arrhythmias and cardiac complications).

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## **Data analysis plan**

The first list of variables to input has already been agreed upon and includes a set of 145 variables classified into: demographic data, previous diagnoses and risk factors, previous treatments, symptoms and pre-infection functional status, clinical data at the time of hospitalisation (examination, blood tests and complementary tests), treatments and surgeries during infection-hospitalisation, duration of processes, hospitalisations, ICU care, and events. We expect to complete the registry with follow-up variables not defined yet. The main grouping and comparison variables established for the main objective are variables regarding infection severity (need of hospitalisation, admission to ICU) and regarding complications (Covid-19-related mortality or heart-disease-related mortality). Statistical analysis includes a descriptive part, association analysis, survival analysis and multivariate analysis. Stats analysis will be performed every 2 weeks (first 3 mo) and then every 2 months.

## Documents

### **Study, other information**

[List of centres 21April2020a.pdf](#) (109.05 KB)

## 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)**

Administrative healthcare records (e.g., claims)

Disease registry

Other

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## **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

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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