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

First published: 21/04/2020

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/35231

EU PAS number

EUPAS34756

Study ID

35231

DARWIN EU® study

No

Study countries

☐ Argentina

- [ ] Brazil
- [ ] Greece
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

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)

Study status

Ongoing

Research institutions and networks

Institutions

Hospital Clínico Universitario Virgen de la Arrixaca

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Institution

Networks

CIBERCV

Contact details

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Study timelines

Date when funding contract was signed

Planned: 03/04/2020

Actual: 01/05/2020

Study start date

Planned: 03/04/2020

Actual: 16/04/2020

Data analysis start date

Planned: 20/04/2020

Date of interim report, if expected

Planned: 11/05/2020

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

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

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

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 patiets 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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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).

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

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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