Association of ACE inhibitors and AT1R blockers and prognosis in hospitalized COVID-19 patients: a cohort study in Italy (ITA-COVID: RAS INHIBITORS)

First published: 03/04/2020

Last updated: 11/05/2020

Study Finalised

Administrative details

EU PAS number

EUPAS34541

Study ID

35260

DARWIN EU® study

No

Study countries

☐ Italy

Study description

This observational study will use Italian claims databases from 5 catchment areas (Lombardy, Veneto and Lazio Regions as well as Modena and Reggio Emilia Local Health Unit) linked to COVID-19 patient registries in the same catchment areas. The aim of the study is to evaluate whether treatment with ACE-inhibitors or angiotension receptor blockers modifies the clinical progression or prognosis of patients infected with COVID-19 who have been hospitalised.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacoepidemiology Unit - National Centre for Epidemiology, Surveillance and Health Promotion, Istituto Superiore di Sanità (ISS)

Italy

First published: 23/03/2010

Last updated: 18/09/2023

Institution **Educational Institution** **Laboratory/Research/Testing facility**

ENCePP partner

Multiple centres: 5 centres are involved in the study

Contact details

Study institution contact

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Study contact

trifirog@unime.it

Primary lead investigator

Stefania Spila Alegiani

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2020

Actual: 31/03/2020

Study start date

Planned: 15/04/2020

Actual: 31/03/2020

Date of interim report, if expected

Planned: 15/05/2020

Date of final study report
Planned: 30/05/2020

Actual: 30/04/2020

Sources of funding

- Other

More details on funding

Self-funded

Study protocol

Protocollo studio ISS_english_ENCePP_redacted.pdf(281.35 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study is to verify if the use of ACE inhibitors and/or angiotensin receptor blockers before COVID-19 outbreak may modify the clinical course of infection and prognosis of hospitalized SARS-CoV-2 infected patients in Italy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C09) AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

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Population studied

Short description of the study population

A cohort study will be conducted in several Italian regions and local health units (LHU). All patients aged 18 years and older who are hospitalized for a COVID-19 confirmed diagnosis will be included.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

COVID-19 patients

Estimated number of subjects

21000000

Study design details

Outcomes

Death, intensive care unit (ICU) admission, and length of ICU stay.

Data analysis plan

Data will be described using frequencies, percentage, mean with standard deviations (or median with interquartile range, where appropriate). The association between ACE inhibitors and/or AT1R blockers and the study outcomes will be analyzed.

Data management

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 source(s), other

Italian National Health System claims databases

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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