Association of alpha-1 blocker (α-1B) on coronavirus disease (COVID-19) susceptibility and severity

First published: 11/07/2020

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS36231

Study ID

40308

DARWIN EU® study

No

Study countries

- ☐ Spain
- ☐ United Kingdom
- ☐ United States

Study description

This study will evaluate the effect of alpha-1 blocker (α-1B) exposure on the risk of contracting COVID-19 infection and of subsequently requiring hospitalization and intensive services such as mechanical ventilation. The analysis will be undertaken across a federated multi-national network of electronic health records and administrative claims from primary care and secondary care that have been mapped to the Observational Medical Outcomes Partnership Common Data Model in collaboration with the Observational Health Data Sciences and Informatics (OHDSI) and European Health Data and Evidence Network (EHDEN) initiatives. These data reflect the clinical experience of patients from Spain, the United Kingdom, and the United States of America as data becomes available. We will use a prevalent user cohort design to estimate the relative risk of each outcome using an on-treatment analysis of monotherapy. Data driven approaches will be used to identify potential covariates for inclusion in matched or stratified propensity score models identified using regularized logistic regression. Large-scale propensity score matching and stratification strategies that allow balancing on a large number of baseline potential confounders will be used in addition to negative control outcomes to allow for evaluating residual bias in the study design as a whole as a diagnostic step.

Study status

Finalised

Research institutions and networks

Networks

Observational Health Data Sciences and Informatics (OHDSI) Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

European Health Data Evidence Network (EHDEN)

Netherlands

First published: 01/02/2024

Last updated: 04/08/2025

Network

Contact details

Study institution contact

Marc Suchard msuchard@ucla.edu

Study contact

msuchard@ucla.edu

Primary lead investigator

Marc Suchard

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 07/07/2020

Actual: 07/07/2020

Study start date
Planned: 08/07/2020

Actual: 08/07/2020

Date of final study report
Planned: 30/10/2020

Actual: 24/03/2021

Sources of funding

- Other

More details on funding

IMI EHDEN

Study protocol

alpha_blocker_study_protocol (1).pdf (584.75 KB)

alpha_blocker_study_protocol.pdf (254.48 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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To estimate the association between prevalent use of alpha-1 blockers (α-1B) and the risk of contracting COVID-19 infection and of subsequently requiring hospitalization and intensive services such as mechanical ventilation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G04C) DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Medical condition to be studied

Benign prostatic hyperplasia

Population studied

Short description of the study population

The cohort will consist of adult male patients aged 18 years and over who receive at least one eligible prescription for an exposure drug between 1st November 2019 and 31st January 2020 (with index date set as the last prescription in this window) and are observable in each database for at least one year prior to the index date. To minimize confounding by indication, patients are required to have a history of benign prostatic hyperplasia at any

point prior to or including the index date and to be prescribed medication (α-1B or 5-αRI) as treatment. Cohort exit will be the earliest of: the occurrence of an outcome event; the end of exposure; death; loss or deregistration from the database; or date of last data collection.

Age groups

- 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

Other

Special population of interest, other

Benign prostate hyperplasia patients

Estimated number of subjects

20000

Study design details

Outcomes

The primary outcomes of interest will be an incident of COVID-19 diagnosis or SARS-CoV-2 positive test 1) without hospitalization, 2) with hospitalization, and 3) requiring intensive in-patient services such as mechanical ventilation. The detailed definitions of these outcomes are given in Appendix 1.

Data analysis plan

We will estimate the relative risk of each outcome using an on-treatment analysis for the target exposure (α-1B) against the comparator exposure (5-αRI) in patients with BPH. We will describe patient characteristics (prevalence) for each cohort comparison and data source. To adjust for measured confounding, propensity score models for each class pair and data source will be created using a data-driven process using regularized logistic regression when target and comparator cohorts contain at least 500 patients within each data source. This process allows the data to decide which combinations of baseline patient characteristics, including demographics and previous conditions, drug exposures, procedures, and health-service-use behaviors are most predictive of treatment assignment. For cohorts with fewer than 500 patients, we will build propensity score models using gender and age categorized in 5-year groups, and index month examining for any heterogeneity.

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.

Signed checklist for study protocols

ENCePPChecklistforStudyProtocols (1).pdf (224.47 KB)

Data sources

Data source(s), other

SIDIAP Spain

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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