Pharmacological risk factors for COVID-19 infection: a matched prospective cohort study of patients in primary care

First published: 10/04/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS34663

Study ID

35329

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Background: There has been speculation that drugs used to manage chronic conditions such as type 2 diabetes and hypertension could lead to increased risk of both COVID-19 infection and deaths related to the infection. On the other hand there is also belief that some medications may be protective (e.g. HCQ). This has been amplified on social media and there is no current evidence to support these hypotheses. In order to provide appropriate guidance for these high risk patients, it is essential that we conduct a pharmaco-epidemiological study to investigate these effects.Aim: This study will aim to identify the effect of current use of various antihypertensive treatments (ACE inhibitors, ARAs and calcium channel blockers), therapies for type 2 diabetes (SGLT2 inhibitors), NSAIDs and hydroxychloroquine on COVID-19 infection rates and related mortality. We will compare the rates and severity (hospitalisation due to COVID-19, mortality) of COVID-19 infection among patients prescribed with the above-mentioned drugs (with an underlying condition indicating a necessity for their prescription) compared to propensity score matched patients prescribed with comparator drugs (with the same underlying condition). Design: Propensity score matched cohort study with active comparators. Target population: Adults aged 50 years and above with a diagnosis of hypertension, type 2 diabetes mellitus, rheumatoid arthritis and osteoarthritis as of 30th Jan 2020. Outcomes: (1) Composite of confirmed, suspected or probable diagnosis of COVID-19(2) Confirmed diagnosis of COVID-19 (3) COVID-19 associated mortality(4) Hospitalization due to COVID-19

Study status

Ongoing

Research institutions and networks

Institutions

University of Birmingham

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Institution

Institute of Applied Health Research

Contact details

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Study timelines

Date when funding contract was signed

Planned: 17/04/2020

Study start date

Planned: 17/04/2020

Actual: 15/05/2020

Data analysis start date

Planned: 17/04/2020

Actual: 15/05/2020

Date of interim report, if expected

Planned: 17/05/2020

Date of final study report

Planned: 17/06/2020

Sources of funding

- Other

More details on funding

TBC

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

Effectiveness study (incl. comparative)

Main study objective:

The overall aim of this study is to investigate the effects of routine medications used to manage underlying chronic conditions on the rate and severity of COVID-19 infection.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C02) ANTIHYPERTENSIVES

ANTIHYPERTENSIVES

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

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(P01BA02) hydroxychloroquine

hydroxychloroquine

(M01AE53) ketoprofen, combinations

ketoprofen, combinations

(A10BA02) metformin

metformin

(B01AC22) prasugrel

prasugrel

(C10BX15) atorvastatin and perindopril

atorvastatin and perindopril

Medical condition to be studied

Type 2 diabetes mellitus

Hypertension

Rheumatoid arthritis

Osteoarthritis

Polycystic ovaries

Atrial fibrillation

Cardiovascular examination

Population studied

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

15000

Study design details

Outcomes

Outcomes: (1) Composite of confirmed, suspected or probable diagnosis of COVID-19(2) Confirmed diagnosis of COVID-19 (3) COVID-19 associated mortality(4) Hospitalization due to COVID-19

Data analysis plan

We will use descriptive statistics to summarize the characteristics of the patients in each of the current prescription cohorts. We will provide the descriptive statistics for the exposure pairs: 1) as derived without matching, 2) after coarsened exact matching, 3) propensity score matching. Crude incidence rates of each outcome will be calculated with 95% CIs. In the primary analysis, we will apply a Cox proportional hazards regression model to determine crude and adjusted hazard ratios (HR) for pharmacological risk modifiers comparing pairs of treatment groups in patients with the underlying indicative condition for each of the outcomes mentioned. In addition, we will report survival curves adjusted for baseline confounders, and/or HRs at increasing periods of follow-up.

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 source(s)

THIN® (The Health Improvement Network®)

Clinical Practice Research Datalink

Data sources (types)

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