Dynamics of prescription drug use, diagnoses and health care utilization after community managed SARS-CoV-2 infection

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/41235

EU PAS number

EUPAS37658

Study ID

41235

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

Using the Danish national health registries, we examine drug use, hospital diagnoses and health care utilization prior to and after SARS-CoV-2 infection among individuals with community managed SARS-CoV-2 infection. Analyses are repeated for an age and sex matched cohort of individuals tested negative for SARS-CoV-2 and individuals hospitalized with SARS-CoV-2 infection.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacoepi center, University of Southern Denmark

Denmark

First published: 22/04/2010

Last updated: 27/07/2023

Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Anton Pottegård

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2020

Actual: 01/10/2020

Study start date

Planned: 27/02/2020

Actual: 27/02/2020

Data analysis start date

Planned: 20/10/2020

Actual: 20/10/2020

Date of final study report

Planned: 15/11/2020

Actual: 10/05/2021

Sources of funding

- Other

More details on funding

University of Southern Denmark

Study protocol

EUPAS37658_protocol initial.pdf(518.59 KB)

protocol-eu-pas-amended3.pdf(522.74 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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Main study objective:

The aim of the study is to examine drug use, hospital diagnoses and health care utilization after SARS-CoV-2 infection.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

SARS-CoV-2 test positive

SARS-CoV-2 test negative

Population studied

Short description of the study population

Any individual with a positive or negative reverse-transcriptase polymerase chain reaction (RTPCR) test for SARS-CoV-2 in Denmark during the period 27-

02-2020 to 31-05-2020 was eligible for inclusion in the study.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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)

Estimated number of subjects

531619

Study design details

Outcomes

Primary outcomes are the initiation of prescription drugs or hospital diagnoses that may represent delayed complication or persisting symptoms to SARS-CoV-2 infection and healthcare utilization after SARS-CoV-2 infection. For a detailed list of all outcomes, please see the study protocol

Data analysis plan

The measure of occurrence for initiation of new medication, reinitiation of medication, first-ever diagnoses and readmissions will be the cumulative incidence proportion (IP) during follow up (duration: 90 days). IP differences comparing individuals with community managed SARS-CoV-2 infection to SARS-

CoV-2 negative individuals and individuals hospitalized for SARS-CoV-2 infection, will be estimated using generalized linear models using a binomial distribution and an identity link. The rates of healthcare utilization (number of visits per 1000 individuals during follow up) will be quantified during the prior comparator period and follow up (duration: 90 days each) for each cohort. Rate ratios, rate differences and exact 95% confidence intervals comparing the prior comparator period to follow up will be calculated for each cohort.

Documents

Study publications

Lund LC, Hallas J, Nielsen H, et al. Post-acute effects of SARS-CoV-2 infection...

Data management

ENCePP Seal

Conflicts of interest of investigators

EUPAS37658_COI.pdf(9.03 KB)

Signed checklist for study protocols

encepp-final.pdf(155.98 KB)

Data sources

Data source(s)

Danish registries (access/analysis)

Data source(s), other

Danish Registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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