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

First published: 19/10/2020
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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 institution 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

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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 data collection

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 data (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