Inhaled corticosteroids and COVID-19 morbidity: Nationwide cohort study

First published: 06/07/2020

Last updated: 11/03/2021

Study Finalised

Administrative details

EU PAS number

EUPAS35897

Study ID

39968

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

Study of corticosteroids in COVID-19 in comparison with influenza.

Study status

Finalised

Research institutions and networks

Institutions

Department of Epidemiology Research, Statens Serum Institut

Denmark

First published: 16/03/2010

Last updated: 24/02/2012

Institution | **EU Institution/Body/Agency** | **Laboratory/Research/Testing facility** | **ENCePP partner**

Pharmacoepi center, University of Southern Denmark

Denmark

First published: 22/04/2010

Last updated: 27/07/2023

Institution | **Educational Institution** | **ENCePP partner**

Statens Serum Institut Copenhagen, Denmark

Contact details

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Study contact

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Primary lead investigator

Anders Husby

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/07/2020

Study start date

Actual: 06/07/2020

Data analysis start date

Actual: 06/07/2020

Date of final study report

Planned: 03/08/2020

Actual: 11/03/2021

Sources of funding

- Other

More details on funding

Various Research councils

Study protocol

COVID_19_inhaled_cs_PROTOCOL_FINAL_EUPAS_P.pdf(531.02 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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The investigate the effect of inhaled corticosteroids on SARS-CoV-2 morbidity.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03BA) Glucocorticoids

Glucocorticoids

Medical condition to be studied

COVID-19

Influenza

Population studied

Short description of the study population

All hospitalized individuals aged 40 years or older in Denmark with a positive SARS-CoV-2 PCR test up to July 16, 2020, were included in our COVID-19 cohort from the date of testing or hospitalization, whichever came latest. The COVID-19 cohort was followed up for ICU admission or death within 30 days from cohort entry. Individuals who tested PCR-positive for influenza during 2010-2018 were included in an equivalent influenza cohort from the date of testing or hospitalization, whichever came latest, and followed up for ICU admission or death within 30 days from cohort entry. For sensitivity analyses, we also constructed nationwide
cohorts of all individuals aged 40 years or older who tested positive for SARS-CoV-2 or influenza while outof-hospital to investigate effect of ICS use in the general population. These cohorts were followed up for hospitalization or death within 30 days from the test date. In addition, we constructed cohorts of SARS-CoV2 or influenza test-positive ICU-patients who were followed up for death within 30 days from admission to ICU, to investigate effect of ICS use among patients with severe illness.

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

COVID-19 patients

Estimated number of subjects

50000

Study design details

Outcomes

We investigate the 30-day hazard ratio of mechanical ventilation or death among users of inhaled corticosteroids (ICS) compared with users of inhaled β2-receptor agonist and/or muscarinic receptor antagonists but not ICS (non-ICS inhaler), or no inhaled pharmaceutical use. The analysis was done for COVID-19 and influenza patients, respectively. Substudy of subtypes of inhaled corticosteroids with regards to the primary outcomes.

Data analysis plan

Our main analysis was conducted among hospitalized test-positive individuals for influenza (in 2010-2018) and COVID-19 (in 2020), respectively. We followed participants for 30 days from the date of testing positive until either mechanical ventilation, death, or loss to follow-up from other causes. We used Cox proportional hazards regression to estimate the hazard ratios of death and mechanical ventilation comparing exposure groups. We estimated 30-day cumulative hazards according to exposure status taking competing risks into account using the Nelson-Aalen estimator. In the Cox models, we took potential confounders into account through direct propensity score adjustment. Propensity scores was estimated using logistic regression of probability of exposure on the above-mentioned covariates as main effects. We estimated separate propensity scores for each exposure group of interest.

Documents

Study results

Association between ICS and COVID19_manuscriptFINAL_eupas.pdf(623.43 KB)

Study publications

Husby A, Pottegård A, Hviid A. Inhaled corticosteroid use in COVID-19. medRxiv…

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)

Danish registries (access/analysis)

Data sources (types)

Disease registry

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection

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