Use of non-steroidal anti-inflammatory drugs and clinical outcome of COVID-19: a Danish nationwide cohort study (NSAID COVID-19)

First published: 21/04/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS34734

Study ID

34735

DARWIN EU® study

No

Study countries

Denmark

Study description

In the early stages of the COVID-19 pandemic in Europe, case reports from southern France described young patients without comorbidities who developed severe COVID-19 after exposure to ibuprofen. This led to warnings against use of ibuprofen and other NSAIDs in patients with COVID-19 by multiple parties, including the French health ministry. However, no data has been published regarding the safety of NSAIDs in COVID-19. We aim to study the association between NSAID use and risk of death in patients with COVID-19. In secondary analyses, associations between NSAIDs and hospitalisation, ICU admission and mechanical ventilation will be investigated. This is a Danish nationwide registry-based cohort study. All individuals tested positive for severe acute respiratory syndrome coronavirus 2 will be followed from the date of positive test and 30 days onward for occurrence of death, and from the date of positive test and 14 days onward for occurrence of hospital admission, ICU admission, and mechanical ventilation. Use of NSAIDs will be compared to non-use using an exposure assessment window of 30 days prior to the positive test. Risks, risk difference and relative risk will be estimated for each outcome.

Study status

Ongoing

Research institutions and networks

Institutions

University of Southern Denmark (SDU)

Denmark

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Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anton Pottegård

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/02/2020

Actual: 27/02/2020

Study start date

Planned: 27/02/2020

Actual: 27/02/2020

Data analysis start date

Planned: 01/06/2020

Date of final study report

Planned: 15/06/2020

Sources of funding

- Other

More details on funding

University of Southern Denmark

Study protocol

protocol-EU-PAS-final.pdf (513.95 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Main study objective:

To study the association between NSAID use and risk of death in patients with COVID-19.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M01AE01) ibuprofen

ibuprofen

Medical condition to be studied

Severe acute respiratory syndrome

Coronavirus infection

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- 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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

7.695

Study design details

Outcomes

30-day mortality after positive RT-PCR for SARS-CoV-2 as identified using the Danish Register of Causes of Deaths, Hospital admission, intensive care unit admission, mechanical ventilation and renal replacement therapy in the 14 days after a positive RT-PCR for SARS-CoV-2.

Data analysis plan

Risk, risk difference, risk ratio estimated using generalized linear models (binomial distribution).

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)

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