The effect of mental disorders and treatment with psychotropic agents on the course of COVID-19 (COVID-19 psychotropics)

First published: 28/10/2020

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS37790

Study ID

39974

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

Beyond the psycho-social consequences of the coronavirus disease 2019 (COVID-19) pandemic, people with severe mental disorders, such as schizophrenia and bipolar disorder have been reported with an up to 2-fold increased 30-days risk of death after a severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) positive test. Recent use of psychotropic agents has also been associated with increased risk of death, varying between 50% in users of antidepressants to a three-fold increase in users of antipsychotics. The importance of maintaining and adjusting pharmacological treatment of people with severe mental disorders during the COVID-19 pandemic has been emphasized. Identifying those drugs with lower risk profiles regarding adverse outcomes to COVID-19 will support guidance of selecting and adjusting acute and maintenance treatment during the COVID-19 pandemic. The present study aims at providing a population-based description of the association and potential differential impact of frequently used psychotropic drugs on the course and outcomes of COVID-19 in people with hospital diagnosed and without hospital diagnosed psychiatric disorders. We hypothesize that psychotropic treatment patterns differ between community-treated COVID-19 patients and hospitalized or deceased COVID-19 patients with lower risks for unfavourable outcomes in users of a) aripiprazole, haloperidol, risperidone or paliperidone as oral or short-acting injectable antipsychotics vs. other oral or depot long-acting antipsychotics, b) short-acting benzodiazepines vs. long-acting benzodiazepines, c) SSRIs vs. tricyclic antidepressants. We will use data from the prospectively collected Danish COVID-19 cohort at Statens Serum Institut including all Danish residents tested by the reverse transcriptase polymerase chain reactions (RT-PCR) for SARS-CoV-2.

Study status

Ongoing

Research institutions and networks

Institutions

Aarhus University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Pharmacoepi center, University of Southern Denmark

Denmark

First published: 22/04/2010

Last updated: 27/07/2023

Institution | Educational Institution | ENCePP partner

Department of Clinical Medicine, Department of Affective Disorders, Aarhus University (AU-ADA)

Denmark

First published: 09/05/2011

Last updated: 27/10/2020

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Christiane Gasse

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/07/2020

Study start date

Actual: 27/02/2020

Data analysis start date

Planned: 29/10/2020

Date of final study report

Planned: 30/04/2021

Sources of funding

- Other

More details on funding

SSI, AU-ADA Pro bono

Study protocol

Protocol_COVID 19 mental disorders_20200924_corr_ENCEPP_signed.pdf(899.94 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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To provide a population-based description of the association and potential differential impact of frequently used psychotropic drugs on the course and outcomes of COVID-19 in people with hospital diagnosed and without hospital diagnosed psychiatric disorders.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05A) ANTIPSYCHOTICS

ANTIPSYCHOTICS

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

(N05B) ANXIOLYTICS

ANXIOLYTICS

(N05CD09) brotizolam

brotizolam

Medical condition to be studied

SARS-CoV-2 test positive

Population studied

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

25000

Study design details

Outcomes

Hospitalization within 14 days and death within -2 to 30 days since the verified positive test, (Among those hospitalized): Length of hospitalization, ICU treatment and ventilation (-2 days before the index date).

Data analysis plan

We will describe the prevalence of specific drug use within 6 months before testing for community treated, hospitalized and deceased patients, stratified by age, sex and psychiatric comorbidity. In the primary analyses, we will investigate the association between cumulative and current psychotropic drug use prior to testing and risk of hospitalization and death using logistic regression analysis among all positively tested individuals. The analyses will be stratified, following clinical and power considerations, by psychiatric diagnoses (any diagnosis) and by individual psychiatric disorders PS methodology will be applied by either matching of adjustment for each drug-outcome association of the respective drug pairs. We will apply formal testing for interactions between psychiatric diagnoses/hospital contacts and psychotropic drug use. We will report crude and adjusted odds ratios (ORs) and 95% confidence intervals (95% CI).

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 source(s), other

Danish Registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

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