The Impact of COVID-19 Pandemic on Drug Use: Implications for Regulatory Intervention Impact Studies

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Study Planned

Administrative details

EU PAS number

EUPAS105538

Study ID

105539

DARWIN EU® study

No

Study countries

- ☐ Lithuania
- ☐ Netherlands
- ☐ United Kingdom

Study description

In the European Union (EU), regulatory interventions known as risk minimisation measures (RMMs) are governed by the guidelines called Good pharmacovigilance practices (GVP). The current GVP guidelines also highlight the necessity to assess the impact of these regulatory interventions. However, in practice, implementing regulatory interventions depends on national and international authorities and might be affected by overlapping events, such as introducing a new competitor medicine. Medicine shortages can also cause perceived changes in medicine use. Therefore, it is challenging to discern whether the observed outcomes are directly caused by the intervention or are part of pre-existing secular trends. The COVID-19 pandemic introduced additional complexity to drug utilisation patterns disrupting the usual prescription and dispensation of medicines which caused changes in drug utilisation and health outcome patterns. In this study, we aim to explore whether the periods of strict pandemic restrictions (e.g. curfews and school closings) impacted drug utilisation patterns. Furthermore, we examine the implications of any disruptions for impact studies using data that includes the COVID pandemic period in the selected countries.

Study status

Planned

Research institutions and networks

Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

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Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

Tomas Lasys t.lasys@uu.nl

Study contact

t.lasys@uu.nl

Primary lead investigator

Helga Gardarsdottir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/06/2023

Study start date

Planned: 15/06/2023

Data analysis start date

Planned: 01/12/2023

Date of final study report
Planned: 01/12/2024

Sources of funding

- Other

More details on funding

Utrecht University (PhD project)

Study protocol

COVID Study Protocol v1.0.pdf (483.59 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:

Drug utilisation

Main study objective:

To assess whether the short- and/or long-term drug utilisation patterns were impacted by the COVID-19 pandemic.

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)

Estimated number of subjects

70000

Study design details

Outcomes

To describe the trends of prescribing the selected medicinal products from January 1, 2017, to December 31, 2023. To identify potential structural breaks in prescribing patterns of selected medicinal products over time. To assess if structural breaks in trends (if they are present) align with restrictions implemented due to the COVID-19 pandemic. To conduct sensitivity analyses to determine what assumptions reduce the probability of detecting structural breaks due to the COVID-19 pandemic in the secular trends of drug use (if they are present).

Data analysis plan

The study design will be a retrospective population-based dynamic cohort study. We will use interrupted time series analysis to identify the potential breaks in drug utilisation patterns before and during the COVID pandemic.

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)

PHARMO Data Network

Clinical Practice Research Datalink

Data source(s), other

Electronic prescriptions database Lithuania

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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