REACT-SCOT Pharmacoepidemiology (REACT-SCOT-PHARM)

First published: 01/06/2020
Last updated: 21/11/2020

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/38213

EU PAS number
EUPAS35558

Study ID
38213

DARWIN EU® study
No

Study countries
United Kingdom

Study description
Observational analysis of the association of COVID-19 with drug exposures: A case control study in the population of Scotland

Study status
Ongoing

Research institution and networks

Institutions

University of Edinburgh

United Kingdom
First published: 23/11/2018
Last updated
04/11/2020

Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

Public Health Scotland Glasgow, Scotland

Contact details

Study institution contact
Helen Colhoun

Study contact

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Primary lead investigator
Helen Colhoun

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
01/05/2020
Actual:
01/05/2020

Study start date
Planned:
01/03/2020
Actual:

01/03/2020

Data analysis start date
Planned:
01/05/2020
Actual:
01/05/2020

Date of interim report, if expected
Planned:
05/06/2020

Date of final study report
Planned:
12/06/2020

Sources of funding

- Other

More details on funding

Public Health Scotland

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:
Disease epidemiology

Main study objective:
A systematic examination of drug exposures and their association with severe COVID-19

Study Design

Non-interventional study design
Case-control

Study drug and medical condition

Medical condition to be studied
COVID-19

Population studied

Age groups
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
30000

Study design details

Outcomes
Severe COVID -19 defined as entry to critical care unit or death within of a positive nucleic acid test for SARS-CoV-2

Data analysis plan
rate ratios estimated by conditional logistic regression

Documents

Study, other information
bnfandicdvulnerablepharmacoepi.pdf(464.4 KB)

Study publications
McKeigue PM, Weir A, Bishop J, McGurnaghan SJ, Kennedy S, McAllister D, Roberts…

Data management

Data sources

Data sources (types)
Administrative data (e.g. claims)
Disease registry
Drug dispensing/prescription data
Other

Data sources (types), other
ECOSS- virology laboratory data covering the population of Scotland.SICSAG- database of all Critical Care Unit AdmissionsPrescribing Information System Scotland- all national dispensed prescriptions. Scottish Morbidity Record 01- all national hospitalisations Rapid- daily hospitalisation returnsNational Records of Scotland registered deaths

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