COVID-19: Viral Pneumonia – Understanding Disease Presentation, Risk Factors and Healthcare Utilization, Including Ventilator and Extracorporeal Membrane Oxygenation (COVID-19: Pneumonia Complications)

First published: 02/04/2020

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Study Planned

Administrative details

EU PAS number

EUPAS34494

Study ID

34495

DARWIN EU® study

No

Study countries

United States

Study description

The coronavirus disease (COVID-19) has reported symptoms as fever, cough, fatigue headache, pneumonia, diarrhea, hemoptysis and dyspnea.1 Pneumonia and consequences thereof are fatal to many of the critically-ill patients. 2Whereas multiple papers have attempted to describe the radiographic differences between COVID-19 pneumonia and other viral pneumonias, differentiating between viral pneumonia and bacterial pneumonia at patient admission is difficult, even for experienced physicians, yet alone differentiating between COVID-19 viral and all other viral pneumonias. 3 4 Large-scale analysis to evaluate patient comorbidities, demographics and risk factors for viral pneumonia, as compared to other pneumonia types, has not been well documented. This study is designed to further our understanding of viral pneumonia to help healthcare systems deal with the COVID-19 pandemic.The rationale for conducting this study is as follows: due to the potentially large COVID-19 population requiring ventilation support, there is a risk that the US healthcare system might be overwhelmed. Models to help understand patients at greater risk for increased healthcare needs or mortality may thus help with policy planning, decisions and treatment.This study will be conducted using the Mercy Electronic Healthcare Data - This data is uniquely fit for purpose as it contains, among other common variables, information such as spirometry data, detailed vitals, exact time when ventilator use is ordered and started.

Study status

Planned

Research institutions and networks

Institutions

Mercy Healthcare System

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Institution

Contact details

Study institution contact

Holy Chantal choly1@its.jnj.com

Study contact

choly1@its.jnj.com

Primary lead investigator

Holy Chantal

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 23/03/2020

Study start date
Planned: 23/03/2020

Date of final study report
Planned: 31/05/2020

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Johnson & Johnson, Mercy Healthcare

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:

Other

If ‘other’, further details on the scope of the study

Risk for ventilator and ECMO needs in patients with pneumonia

Main study objective:

Characterize patients with pneumonia and identify risk factors for ventilator/ECMO need, prolonged ventilator use and mortality

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Pneumonia

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

10000

Study design details

Outcomes

- Evaluate patient demographics, comorbidities, prescription medications and concurrent diagnoses at time of first pneumonia diagnosis (by pneumonia type) - Evaluate patient healthcare utilization and risk of requiring critical-care – including extracorporeal membrane oxygenation (EMO) - mortality, in patients with viral vs other pneumonia (by pneumonia types), - Evaluate risk of patients with a first viral pneumonia diagnosis to also develop other pneumonia types - Evaluate patient demographics, comorbidities, prescription medications, and risk factors for critical-care and mortality in patients with a pneumonia, by type

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Data analysis plan

Descriptive statisticsComparison between pneumonia types (chi square for categorical variable comparison, t-test for continuous variable comparisonLogistic models to evaluate risks for critical care needs and mortality. Regression models to evaluate duration of disease

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 sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Electronic health records from an integrated delivery system, including new variables such as surgical notes, spirometry data, laboratory data, vitals.

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