COVID-19: Risk Factors Associated with Respiratory Support Needs in Patients with Viral Disease (COVID-19: US Ventilator Use)

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Study   Planned

Administrative details

EU PAS number

EUPAS34490

Study ID

34491

DARWIN EU® study

No

Study countries

United States

Study description

Epidemiologic characteristics suggest that 14% cases affected by the coronavirus disease 2019 (COVID-19) are severe, and 5% critical. Management of severe COVID-19 patients is consistent with that provided to patients with viral pneumonia causing respiratory failure and includes lung-protective ventilation strategies and possible mechanical ventilation. Whereas there is significant experience in treatment of severe acute respiratory failure (SARF), the risk factors for SARF are not well characterized. A recent study looked at a composite value of 5 variables (age, dehydration, respiratory failure, orientation, blood pressure) to predict risk for mortality and requirement for mechanical ventilation. This relatively small study was followed by a few studies evaluating risk factors for pneumonia. However, we are not aware of any large population-based study designed to identify risk factors for SARF and/or need for mechanical ventilation. This study is therefore design to identify key patient variables, known at time of admission, as well as medication and procedure use during hospitalization, that may predict risk for need for mechanical ventilation and mortality.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

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Study contact

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Primary lead investigator

Chantal Holy

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/03/2020

Actual: 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 System

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

Progression of disease and risk for device utilization

Main study objective:

Understand risk factors for severe respiratory disease leading to requirement for mechanical ventilator use and ECMO and prolonged mechanical ventilator use and mortality, in patients with influenza, as a proxy for COVID-19.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Influenza

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

200000

Study design details

Outcomes

1) Understand risk factors for severe respiratory disease leading to requirement for mechanical ventilator use and ECMO use that are assessed at the time of first contact with the healthcare systems with a diagnosis of influenza (flu).2) Estimate the incidence of respiratory ventilator use and ECMO use among patients diagnosed with influenza in the Mercy Health population, Understand risk factors for prolonged mechanical ventilator use, ECMO use, and mortality.

Data analysis plan

Logistic models to evaluate risks for ventilator use, extended ventilator use and mortality. If sufficient population size: predictive models.

Data management

ENCePP Seal

Data sources

Data source(s), other

Mercy Healthcare United States

Data sources (types)

Other

Data sources (types), other

Integrated delivery network electronic health record, includes all in- and outpatient care, including laboratory, vitals, surgical notes, medical devices.

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