

PROJECT SUMMARY SHEET

TITLE: EC-COVID (Early CPAP in COVID patients with respiratory failure)

RESEARCH ENTITY: Istituto di Ricerche Farmacologiche Mario Negri IRCCS (*Mario Negri IRCCS Pharmacology Research Institute*)

PROJECT LOCATION: Multicenter project conducted at 26 emergency departments in Italy

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ABSTRACT/SUMMARY

- INTRODUCTION:

The percentage of COVID-19 patients requiring intubation is relatively low (around 5% of cases), but it is associated with a poor prognosis if patients are intubated. Furthermore, as the epidemic progresses the number of intubated patients may be so great as to cause problems for the national health service. It is therefore important to find therapeutic approaches to prevent this from occurring.

- METHOD:

A multicenter, randomized study conducted in the Emergency Department incorporated into an observational cohort study. The interventional portion consists of a randomized, controlled study with the following eligibility criteria: adults, confirmed or suspected COVID-19 infection with one or more of the following symptoms: fever, cough/dyspnea, $SpO_2 < 95\%$ in ambient air ($< 91\%$ if patient has COPD), positive rapid pace walk test, respiratory symptoms or respiratory issue the reason for coming to the Emergency Department. The following conditions must also be present: $PaO_2/FiO_2 > 250$ ratio in ambient air, measured within 1 hour of arrival in the Emergency Department; respiratory rate at rest > 25 breaths/minute; the physician is basically uncertain whether or not to start CPAP for the patient (uncertainty principle).

- OBJECTIVES:

Determine whether early treatment with CPAP in conjunction with current clinical practice can reduce the need for intubation or death in patients with confirmed or suspected COVID-19 infection and respiratory

failure. The primary endpoint of the study is the combination of intubation or death within 7 days of randomization. The secondary endpoint is death within 30 days of randomization.

PROJECT PRESENTATION DATE: 3/11/2020