
Abstract

OBJECTIVE:
Few randomized trials have evaluated the use of non-invasive ventilation (NIV) for early acute respiratory failure (ARF) in non-intensive care unit (ICU) wards. The aim of this study is to test the hypothesis that early NIV for mild-moderate ARF in non-ICU wards can prevent development of severe ARF.

DESIGN:
Pragmatic, parallel group, randomized, controlled, multicenter trial.

SETTING:
Non-intensive care wards of tertiary centers.
PATIENTS:
Non-ICU ward patients with mild to moderate ARF without an established indication for NIV.

INTERVENTIONS:
Patients will be randomized to receive or not receive NIV in addition to best available care.

MEASUREMENTS AND MAIN RESULTS:
We will enroll 520 patients, 260 in each group. The primary endpoint of the study will be the development of severe ARF. Secondary endpoints will be 28-day mortality, length of hospital stay, safety of NIV in non-ICU environments, and a composite endpoint of all in-hospital respiratory complications.

CONCLUSIONS:
This trial will help determine whether the early use of NIV in non-ICU wards can prevent progression from mild-moderate ARF to severe ARF.

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KEYWORDS:
ARF; Acute respiratory failure; NIV; Non-invasive ventilation