Comparison of high flow nasal cannula oxygen and conventional oxygen therapy on ventilatory support duration during acute-on-chronic respiratory failure: study protocol of a multicentre, randomised, controlled trial. The 'HIGH-FLOW ACRF' study

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Résumé en anglais	INTRODUCTION: This study protocol describes a trial designed to investigate whether high-flow heated and humidified nasal oxygen (HFHO) therapy in patients with hypercapnic acute respiratory failure (ARF) reduces the need of non-invasive ventilation (NIV). METHODS AND ANALYSIS: This is an open-label, superiority, international, parallel-group, multicentre randomised controlled two-arm trial, with an internal feasibility pilot phase. 242 patients with hypercapnic ARF requiring NIV admitted to an intensive care unit, an intermediate care or a respiratory care unit will be randomised in a 1:1 ratio to receive HFHO or standard oxygen in between NIV sessions. Randomisation will be centralised and stratified by centre and pH at admission (pH ≤7.25 or >7.25). The primary outcome will be the number of ventilator-free days (VFDs) and alive at day 28 postrandomisation. The secondary outcomes will encompass parameters related to the VFDs, comfort and tolerance variables, hospital length of stay and mortality. VFDs at 28 days postrandomisation will be compared between the two groups by Wilcoxon-Mann-Whitney two-sample rank-sum test in the intention-to-treat population. A sensitivity analysis will be conducted in the population of patients for whom the criteria of switching from NIV to spontaneous breathing, or conversely, are not strictly verified. ETHICS AND DISSEMINATION: The protocol has been approved by the (CPP) (ref CPP17-049a/2017-A01830-53) and will be carried out in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. A trial steering committee will oversee the progress of the study. Findings will be disseminated through national and international scientific conferences, and publication in peer-reviewed journals. TRIAL REGISTRATION NUMBER: NCT03406572.
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