Onderzoeksprotocol

(voor aanvraag niet-WMO verklaring)

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Algemene gegevens

Titel	Effect on nebulization practices after the implementation of a consensus based decision support tool in Mechanically Ventilated ICU Patients: a multi-center study.
Datum	11-08-2025
Versienummer	2
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Opdrachtgever (verrichter)	Amsterdam University Medical Centers Intensive Care

Onderzoekgegevens

Rationale	Nebulization is a commonly used in Intensive Care Unit (ICU) patients receiving invasive ventilation to manage secretion accumulation resulting from impaired mucociliary clearance, mucosal dehydration and weakened cough reflex. Our previous nationwide survey (yet to be published) revealed considerable practice variation across Dutch ICUs, with difference in indication, frequency and choice of agents. Notably, many currents practice appear misaligned with available evidence, including findings from the NEBULAE trial (1). This trial showed that routine nebulization does not improve clinical outcomes compared to on-indication use, while contributing to adverse effects, increased costs and treatment burden. This variation underscores a persistent gap between evidence-based recommendations and clinical practice, likely driven by the absence of standardized protocols, inconsistent clinical reasoning and organizational barriers. To bridge this gap, we conducted a Delphi study amongst experts to develop consensus on appropriate indications and best practices for nebulization in invasively ventilated ICU patients. Together with the available evidence on nebulization practices, the results are used to

	develop a pragmatic, consensus based decision tool designed to guide ICU professionals in the indication, initiation and evaluation of nebulization therapy. This aims is to reduce unnecessary, routine use of nebulization by promoting targeted, need-based application. With a tailored implementation toolbox this decision tool will be implemented in a selection of ICUs that participated in the original survey. Our aim is to assess the uptake and compliance with the decision tool, and to evaluate whether its implementation led to a reduction in inappropriate nebulization. 1. van Meenen DMP, van der Hoeven SM, Binnekade JM, de Borgie C, Merkus MP, Bosch FH, et al. Effect of On-Demand vs Routine Nebulization of Acetylcysteine With Salbutamol on Ventilator-Free Days in Intensive Care Unit Patients Receiving Invasive Ventilation: A Randomized Clinical Trial. JAMA. 2018;319(10):993-1001.
Doel	To assess the change in nebulization practices after the implementation of a consensus-based decision tool, and to evaluate whether its implementation led to a reduction in routinely nebulization.
Studie design	This nationwide (the Netherlands) before and after study to assess the uptake and compliance to the consensus-based nebulization decision tool
Studie populatie	The study population consists of five selected ICUs across the Netherlands where the consensus-based nebulization decision tool will be implemented. Participating centers either routinely administer nebulization or lack structured evaluation of nebulization practices.
Beoogd aantal proefpersonen Amsterdam UMC	-
Beoogd aantal proefpersonen in Nederland	-
Inclusiecriteria	ICUs that participated in our national survey and indicated willingness to participate in this follow-up study. From these centers, we will select centers for this study where either routinely nebulization is applied, or those lacking structured evaluation moments.
Exclusiecriteria	None
Aantal proefpersonen/ sample grootte	5 ICUs

Werving proefpersonen	Dutch ICUs who indicated willingness to participate in the follow-up implementation study of the national survey and who met the inclusion criteria (see above). Participating ICUs will receive an e-mail confirming their selection, which contains detailed information about the study's aim and procedures, and explicitly requests consent for participation from the department heads.
Interventie	Prior to implementation of the consensus-based nebulization decision support tool, baseline nebulization practices will be assessed. Therefore, all nebulization instances will be recorded twice weekly over four pre-intervention time points (corresponding to a two-week pre-implementation period) to quantify the frequency and indications for nebulization in current practice. All assessments will be conducted by a designated member of our research team, and data collection will be coordinated in collaboration with the participating ICUs. Subsequently, the consensus-based decision support tool will be implemented using the site-specific implementation toolboxes. Following a transition period of four weeks after full implementation, post-intervention data will be collected. This includes indications for nebulization, frequency, on-demand use recorded twice weekly over four post-intervention time points (again covering two weeks in total). During the intervention period, participating ICUs will receive regular feedback on their nebulization practices, such as profess in reducing routine nebulization and adherence to the decision support tool.
Standaardzorg / Standaardbehandeling	Not applicable
Studie eindpunten	The primary endpoint is the proportion of routine (non-indicated) nebulizations before and after implementation of the decision support tool. Secondary endpoint include change in nebulization practice after implementation of the decision support tool.
Studie parameters	During the pre- and post-implementation phase, all administered nebulization decisions will be recorded, including the indication for administration, the execution of treatment, and any evaluation of its effect. We will assess if a change in applied indications, frequency and routine nebulization occurs after the implementation of the expert-consensus based decision tool. - Total number of eligible nebulization decisions during the point-prevalence measurements (pre- and post-implementation). - Timepoint and context of each nebulization decision (e.g. indication, initiation or evaluation, type of nebulization medication, patient category (medical or surgical)). - Proportion of routine (non-indicated) nebulization before and after the implementation - ICU characteristics (academic or non-academic and size (number of beds clustered)).
Statistische analyses	Categorical variables are expressed as number and percentage (%). Continuous data will be expressed as mean with standard deviation

	(SD) or as median with interquartile range (IQR) as appropriate. Normality of data will be assessed using Q-Q plots. A Chi-square test will be used to compare categorial variables between groups, while ANOVA or Kruskal-Wallis test will be used to compare continuous variables. A p-value of 0.05 will be considered to be statistical significant. All statistical analysis will be performed with RStudio (R version 4.3.2). The proportion of eligible nebulization decisions in which the decision-tool was applied as intended will be calculated with corresponding 95% confidence intervals using the Clopper-Pearson method.
Belasting voor de proefpersoon	The use of the decision-tool will take place during routine care and is designed to support current airway management and nebulization practices. While the introduction and use of a new tool may temporarily lead to a slight increase in workload, we think this burden is minimal. No additional invasive or time-consuming procedures are required from ICU staff as part of this study.
Risico voor de proefpersoon	None
Voordelen deelname aan het onderzoek	Participation in this study offers several benefits for ICU staff and patient care. The study brings focused attention to mechanical ventilation management, specifically evidence-based practices in airway care and nebulization. Using the nebulization decision-tool itself functions as an educational intervention, increasing knowledge and awareness among healthcare professionals. Additionally, the eventual implementation of the toolbox may lead to a reduction in unnecessary nebulization, potentially saving time, materials, and reducing workload.
Nadelen deelname aan het onderzoek	None
Vergoeding voor de proefpersoon	None
Administratieve aspecten	Only data on nebulization instances are collected in Castor EDC; no patient-identifiable information or healthcare professional data are gathered. Data are collected and processed exclusively at the center level, with no possibility of tracing results back to individual staff members. Any feedback provided to participating centers is aggregated and not traceable to individuals. Study sites are pseudonymized. All data will be stored and analyzed within the ICT domain of Amsterdam UMC and retained for a maximum of 10 years.
Publicatiebeleid en amendementen	The results of this study will be published in a scientific, peer-reviewed journal.

Overige punten van belang voor de Niet-WMO toetsingscommissie	The study does not assess whether individual healthcare professionals have administered nebulization appropriately or justifiably, as no national guideline for nebulization exists. We will evaluate the indications for nebulization and aim to assess changes in these indications and practices after implementing our expert consensus–based guideline developed in the recent Delphi study. No data from individual staff members are collected, and staff do not participate as research subjects. Data collection is limited to the center level and concerns nebulization practices only. No surveys or questionnaires are distributed among staff in the context of this study, and no staff data are used. Prior to participation, each center will receive an information letter by email, and study activities will only commence after explicit consent is obtained from the ICU.