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## How post-extubation after COVID-19 affects voice and swallowing

**ID of request:** 26004  
**Date of request:** 9th November, 2020  
**Date of completion:** 16th November, 2020

If you would like to request any articles or any further help, please contact:  Lynne Mackie at [lynne.mackie2@nhs.net](mailto:lynne.mackie2@nhs.net)

Please acknowledge this work in any resulting paper or presentation as: Evidence search: How post-extubation after COVID-19 affects voice and swallowing. Lynne Mackie. (16th November, 2020). London , UK: Barts Health Knowledge and Library Services.

**Sources searched**  
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## A. Original Research

1. **A Phase 3 Open-label, Randomized, Controlled Study to Evaluate the Efficacy and Safety of Intravenously Administered Ravulizumab Compared with Best Supportive Care in Patients with COVID-19 Severe Pneumonia, Acute Lung Injury, or Acute Respiratory Distress Syndrome: A structured summary of a study protocol for a randomised controlled trial.**  
   Smith Keisha Trials 2020;21(1):639.

OBJECTIVESPrimary Objective • To evaluate the effect of ravulizumab, a long-acting complement (C5) inhibitor plus best supportive care (BSC) compared with BSC alone on the survival of patients with COVID-19. Secondary Objectives • Number of days free of mechanical ventilation at Day 29 • Duration of intensive care unit stay at Day 29 • Change from baseline in Sequential Organ Failure Assessment (SOFA) score at Day 29 • Change from baseline in peripheral capillary oxygen saturation/ fraction of inspired oxygen (SpO2 /FiO2) at Day 29 • Duration of hospitalization at Day 29 • Survival (based on all-cause mortality) at Day 60 and Day 90 Safety • Incidence of treatment-emergent adverse events and treatment-emergent serious adverse events. PK/PD/Immunogenicity • Change in serum ravulizumab concentrations over time • Change in serum free and total C5 concentrations over time • Incidence and titer of anti-ALXN1210 antibodies Biomarkers • Change in absolute level of soluble biomarkers in blood associated with complement activation, inflammatory processes, and hypercoagulable states over time Exploratory • Incidence of progression to renal failure requiring dialysis at Day 29 • Time to clinical improvement (based on a modified 6-point ordinal scale) over 29 days • SF-12 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores at Day 29 (or discharge), Day 60, and Day 90 • EuroQol 5-dimension 5-level (EQ-5D-5L) scores at Day 29 (or discharge), Day 60, and Day 90 TRIAL DESIGN: This is a multicenter Phase 3, open-label, randomized, controlled, study. The study is being conducted in acute care hospital settings in the United States, United Kingdom, Spain, France, Germany, and Japan.PARTICIPANTSMale or female patients at least 18 years of age, weighing ≥ 40 kg, admitted to a designated hospital facility for treatment will be screened for eligibility in this study. Key Inclusion criteria • Confirmed diagnosis of SARS-CoV-2 infection (eg, via polymerase chain reaction [PCR] and/or antibody test) presenting as severe COVID-19 requiring hospitalization • Severe pneumonia, acute lung injury, or ARDS confirmed by computed tomography (CT) or X-ray at Screening or within the 3 days prior to Screening, as part of the patient's routine clinical care • Respiratory distress requiring mechanical ventilation, which can be either invasive (requiring endotracheal intubation) or non-invasive (with continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BiPAP]) Key Exclusion criteria • Patient is not expected to survive for more than 24 hours • Patient is on invasive mechanical ventilation with intubation for more than 48 hours prior to Screening • Severe pre-existing cardiac disease (ie, NYHA Class 3 or Class 4, acute coronary syndrome, or persistent ventricular tachyarrhythmias) • Patient has an unresolved Neisseria meningitidis infection Excluded medications and therapies • Current treatment with a complement inhibitor • Intravenous immunoglobulin (IVIg) within 4 weeks prior to randomization on Day 1 Excluded prior/concurrent clinical study experience • Treatment with investigational therapy in a clinical study within 30 days before randomization, or within 5 half-lives of that investigational therapy, whichever is greater • Exceptions a. Investigational therapies will be allowed if received as part of best supportive care through an expanded access protocol or emergency approval for the treatment of COVID-19. b. Investigational antiviral therapies (such as remdesivir) will be allowed even if received as part of a clinical study.INTERVENTION AND COMPARATORThe study consists of a Screening Period of up to 3 days, a Primary Evaluation Period of 4 weeks, a final assessment at Day 29, and a Follow-up Period of 8 weeks. For patients randomized to ravulizumab plus BSC, a weight-based dose of ravulizumab (≥40 to < 60 kg/2400 mg, 60 to < 100 kg/2700 mg, ≥ 100 kg/3000 mg) will be administered on Day 1. On Day 5 and Day 10, additional doses of 600 mg (≥40 to <60 kg) or 900 mg (>60 kg) ravulizumab will be administered and on Day 15 patients will receive 900 mg ravulizumab. There is no active or placebo comparator in this open-label clinical trial. The total duration of each patient's participation is anticipated to be approximately 3 months.MAIN OUTCOMESThe primary efficacy outcome of this study is survival (based on all-cause mortality) at Day 29.RANDOMISATIONPatients will be randomized in a 2:1 ratio (ravulizumab plus BSC:BSC alone). Randomization will be stratified by intubated or not intubated on Day 1. Computer-generated randomization lists will be prepared by a third party under the direction of the sponsor. Investigators, or designees, will enrol patients and then obtain randomization codes using an interactive voice/web response system. The block size will be kept concealed so that investigators cannot select patients for a particular treatment assignment. Blinding (masking): This is an open-label study. Numbers to be randomised (sample size): Approximately 270 patients will be randomly assigned in a 2:1 ratio to ravulizumab plus BSC (n=180) or BSC alone (n=90).TRIAL STATUSProtocol Number: ALXN1210-COV-305 Original Protocol: 09 Apr 2020 Protocol Amendment 1 (Global): 13 Apr 2020 Protocol Amendment 2 (Global): 17 Apr 2020 Protocol Amendment 3 (Global): 09 Jun 2020 Recruitment is currently ongoing. Recruitment was initiated on 11 May 2020. We expect recruitment to be completed by 30 Nov 2020.TRIAL REGISTRATIONClinicaltrials.gov: Protocol Registry Number: NCT04369469 ; First posted; 30 Apr 2020 EU Clinical Trials Register: EudraCT Number: https://www.clinicaltrialsregister.eu/ctr-search/search?query=ALXN1210-COV-305 , Start date: 07 May 2020 FULL PROTOCOL: The full redacted protocol is attached as an additional file, accessible from the Trials website (Additional file 1). In the interest in expediting dissemination of this material, the familiar formatting has been eliminated; this Letter serves as a summary of the key elements of the full protocol.

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1. **Decision kinesitherapique : Alexandre L. 57 ans : Kinesitherapie et Covid-19 en reanimation, de la phase aigue a la rehabilitationDecision physiotherapy workshop: Alexandre L. 57 years old. Physiotherapy and Covid-19 ICU patient from acute respiratory distress syndrome to rehabilitation**  
   Freynet A. Kinesitherapie 2020;20(223):38-44.

A 57-year-old man is hospitalized in intensive care for an acute respiratory distress syndrome related to a Covid-19 infection. After a first phase during which the patient is sedated and nerve-blocked, physiotherapy consists in passively mobilizing the patient, participating in the prone position, respiratory physiotherapy is not necessary. In a second step, extubation is possible and several aspects are developed: respiratory physiotherapy, oxygenation, swallowing and rehabilitation. However, damage to the lung significantly decreases oxygen saturation during exercise. High-flow nasal oxygenation and/or non-invasive ventilation (NIV) can optimize rehabilitation in this patient with a still precarious respiratory function. Evidence index (EVID-i): 3.2.<br/>Copyright &#xa9; 2020 Elsevier Masson SAS

1. **How COVID-19 Patients Were Moved to Speak: A Rehabilitation Interdisciplinary Case Series.**  
   Mooney Brianne HSS journal : the musculoskeletal journal of Hospital for Special Surgery 2020;:1-8.

BackgroundUp to 36% of patients admitted to the ICU for COVID-19 require tracheostomy. While the literature recommends the use of multidisciplinary teams in the management of patients with tracheostomy for other diseases, little is known on the collaborative administration of physical therapy and speech language pathology services in the COVID-19 population.PurposeWe sought to determine the outcomes of a collaboration between physical therapy (PT) and speech language pathology (SLP) in the treatment of patients who underwent tracheostomy placement as part of their treatment for COVID-19 at our facility.MethodsWe conducted a retrospective case series on patients with COVID-19 who had a tracheostomy. We included patients who had undergone mechanical ventilation for 14 days or longer, had a surgical tracheostomy, been discharged from intensive care to a medical unit, and received PT and SLP referrals. We compiled retrospective data from electronic medical records, analyzing days from tracheostomy to achievement of PT and SLP functional milestones, including mobility, communication, and swallowing. Of six critically ill patients with COVID-19 who had tracheostomy placement at our facility, three met inclusion criteria: patient 1, a 33-year-old woman; patient 2, an 84-year-old man; and patient 3, an 81-year-old man. For all patients, PT interventions focused on breathing mechanics, secretion clearance, posture, sitting balance, and upper and lower extremity strengthening. SLP interventions focused on cognitive reorganization, verbal and nonverbal communication, secretion management, and swallowing function. Intensity and duration of the sessions were adapted according to patient response and level of fatigue.ResultsWe found that time to tracheostomy from intubation for the three patients was 23 days, 20 days, and 24 days, respectively. Time from tracheostomy insertion to weaning from ventilator was 9 days for patient 1, and 5 days for patient 2 and patient 3. Regarding time to achieve functional PT and SLP milestones, all patients achieved upright sitting with PT prior to achieving initial SLP milestone of voicing with finger occlusion. Variations in progression to swallowing trials were patient specific and due to respiratory instability, cognitive deficits, and limitations in production of an effortful swallow. Patient participation in therapy sessions improved following establishment of oral verbal communication.ConclusionInterdisciplinary cooperation and synchronized implementation of PT and SLP interventions in three COVID-19 patients following prolonged intubation facilitated participation in treatment and achievement of functional milestones. Further study is warranted.

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1. **Laryngeal complications of COVID-19**  
   Naunheim M.R. Laryngoscope Investigative Otolaryngology 2020;:No page numbers.

Objective: To describe and visually depict laryngeal complications in patients recovering from coronavirus disease 2019 (COVID-19) infection along with associated patient characteristics. Study design: Prospective patient series. <br/>Setting(s): Tertiary laryngology care centers. Subjects and methods: Twenty consecutive patients aged 18 years or older presenting with laryngological complaints following recent COVID-19 infection were included. Patient demographics, comorbid medical conditions, COVID-19 diagnosis dates, symptoms, intubation, and tracheostomy status, along with subsequent laryngological symptoms related to voice, airway, and swallowing were collected. Findings on laryngoscopy and stroboscopy were included, if performed. <br/>Result(s): Of the 20 patients enrolled, 65% had been intubated for an average duration of 21.8 days and 69.2% requiring prone-position mechanical ventilation. Voice-related complaints were the most common presenting symptom, followed by those related to swallowing and breathing. All patients who underwent flexible laryngoscopy demonstrated laryngeal abnormalities, most frequently in the glottis (93.8%), and those who underwent stroboscopy had abnormalities in mucosal wave (87.5%), periodicity (75%), closure (50%), and symmetry (50%). Unilateral vocal fold immobility was the most common diagnosis (40%), along with posterior glottic (15%) and subglottic (10%) stenoses. 45% of patients underwent further procedural intervention in the operating room or office. Many findings were suggestive of intubation-related injury. <br/>Conclusion(s): Prolonged intubation with prone-positioning commonly employed in COVID-19 respiratory failure can lead to significant laryngeal complications with associated difficulties in voice, airway, and swallowing. The high percentage of glottic injuries underscores the importance of stroboscopic examination. Otolaryngologists must be prepared to manage these complications in patients recovering from COVID-19. <br/>Level of Evidence: IV.<br/>Copyright &#xa9; 2020 The Authors. Laryngoscope Investigative Otolaryngology published by Wiley Periodicals LLC on behalf of The Triological Society.

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1. **Multidisciplinary Safety Recommendations After Tracheostomy During COVID-19 Pandemic: State of the Art Review.**  
   Meister Kara D. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery 2020;:194599820961990.

OBJECTIVEIn the chronic phase of the COVID-19 pandemic, questions have arisen regarding the care of patients with a tracheostomy and downstream management. This review addresses gaps in the literature regarding posttracheostomy care, emphasizing safety of multidisciplinary teams, coordinating complex care needs, and identifying and managing late complications of prolonged intubation and tracheostomy.DATA SOURCESPubMed, Cochrane Library, Scopus, Google Scholar, institutional guidance documents.REVIEW METHODSLiterature through June 2020 on the care of patients with a tracheostomy was reviewed, including consensus statements, clinical practice guidelines, institutional guidance, and scientific literature on COVID-19 and SARS-CoV-2 virology and immunology. Where data were lacking, expert opinions were aggregated and adjudicated to arrive at consensus recommendations.CONCLUSIONSBest practices in caring for patients after a tracheostomy during the COVID-19 pandemic are multifaceted, encompassing precautions during aerosol-generating procedures; minimizing exposure risks to health care workers, caregivers, and patients; ensuring safe, timely tracheostomy care; and identifying and managing laryngotracheal injury, such as vocal fold injury, posterior glottic stenosis, and subglottic stenosis that may affect speech, swallowing, and airway protection. We present recommended approaches to tracheostomy care, outlining modifications to conventional algorithms, raising vigilance for heightened risks of bleeding or other complications, and offering recommendations for personal protective equipment, equipment, care protocols, and personnel.IMPLICATIONS FOR PRACTICETreatment of patients with a tracheostomy in the COVID-19 pandemic requires foresight and may rival procedural considerations in tracheostomy in their complexity. By considering patient-specific factors, mitigating transmission risks, optimizing the clinical environment, and detecting late manifestations of severe COVID-19, clinicians can ensure due vigilance and quality care.

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1. **Postintubation Dysphagia During COVID-19 Outbreak-Contemporary Review.**  
   Frajkova Zofia Dysphagia 2020;35(4):549-557.

The COVID-19 is a global pandemic. Its rapid dissemination and serious course require a novel approach to healthcare practices. Severe disease progression is often associated with the development of the Acute Respiratory Distress Syndrome and may require some form of respiratory support, including endotracheal intubation, mechanical ventilation, and enteral nutrition through a nasogastric tube. These conditions increase the risk of dysphagia, aspiration, and aspiration pneumonia. The data on the incidence and risks of dysphagia associated with COVID-19 are not yet available. However, it is assumed that these patients are at high risk, because of respiratory symptoms and reduced lung function. These findings may exacerbate swallowing deficits. The aim of this review is to summarize available information on possible mechanisms of postintubation dysphagia in COVID-19 patients. Recommendations regarding the diagnosis and management of postintubation dysphagia in COVID-19 patients are described in this contemporary review.

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1. **RECOVERY- Respiratory Support: Respiratory Strategies for patients with suspected or proven COVID-19 respiratory failure; Continuous Positive Airway Pressure, High-flow Nasal Oxygen, and standard care: A structured summary of a study protocol for a randomised controlled trial.**  
   Perkins Gavin D. Trials 2020;21(1):687.

OBJECTIVEThe trial objective is to determine if Continuous Positive Airway Pressure (CPAP) or High-Flow Nasal Oxygen (HFNO) is clinically effective compared to standard oxygen therapy in patients with confirmed or suspected COVID-19.TRIAL DESIGNAdaptive (group-sequential), parallel group, pragmatic, superiority randomised controlled, open-label, multi-centre, effectiveness trial.PARTICIPANTSThe trial is being conducted across approximately 60 hospitals across England, Wales, Scotland, and Northern Ireland. Inpatients at participating hospitals are eligible to participate if they have respiratory failure with suspected or proven COVID-19, and meet all of the inclusion criteria and none of the exclusion criteria.INCLUSION CRITERIA1) Adults ≥ 18 years; 2) Admitted to hospital with suspected or proven COVID-19; 3) Receiving oxygen with fraction of inspired oxygen (FiO2) ≥0.4 and peripheral oxygen saturation (SpO2) ≤94%; and 4) Plan for escalation to tracheal intubation if needed.EXCLUSION CRITERIA1) Planned tracheal intubation and mechanical ventilation imminent within 1 hour; 2) Known or clinically apparent pregnancy; 3) Any absolute contraindication to CPAP or HFNO; 4) Decision not to intubate due to ceiling of treatment or withdrawal of treatment anticipated; and 5) Equipment for both CPAP and HFNO not available.INTERVENTION AND COMPARATORIntervention one: Continuous positive airway pressure delivered by any device. Set-up and therapy titration is not protocolised and is delivered in accordance with clinical discretion. Intervention two: High-flow nasal oxygen delivered by any device. Set-up and therapy titration is not protocolised and is delivered in accordance with clinical discretion. Comparator group: Standard care- oxygen delivered by face mask or nasal cannula (excluding the use of continuous positive airway pressure or high-flow nasal oxygen). Set-up and therapy titration is not protocolised and is delivered in accordance with clinical discretion. Intervention delivery continues up to the point of death, tracheal intubation, or clinical determination that there is no ongoing need (palliation or improvement).MAIN OUTCOMESThe primary outcome is a composite outcome comprising tracheal intubation or mortality within 30 days following randomisation. Secondary outcomes include tracheal intubation rate, time to tracheal intubation, duration of invasive ventilation, mortality rate, time to mortality, length of hospital stay, and length of critical care stay.RANDOMISATIONParticipants are randomised in a 1:1:1 ratio to receive either continuous positive airway pressure, high-flow nasal oxygen or standard care. Due to the challenging environment of study delivery, a specific intervention may not always be available at the hospital site. The study uses two integrated randomisation systems to allow, where required, the site to randomise between all three interventions, between CPAP and standard care, and between HFNO and standard care. System integration ensures maintenance of balance between interventions. Randomisation is performed using a telephone-based interactive voice response system to maintain allocation concealment. The randomisation sequence was computer-generated using the minimisation method. Participant randomisation is stratified by site, gender (M/F), and age (<50, >=50 years).BLINDING (MASKING)The nature of the trial interventions precludes blinding of the researcher, patient and clinical team. Primary and secondary outcomes are all objective outcomes, thereby minimising the risk of detection bias.NUMBERS TO BE RANDOMISED (SAMPLE SIZE)4002 participants (1334 to be randomized to each of the three study arms) TRIAL STATUS: Current protocol: Version 4.0, 29th May 2020. Recruitment began on April 6, 2020 and is anticipated to be complete by April 5, 2021. The trial has been awarded Urgent Public Health status by the National Institute of Health Research on 13th April 2020.TRIAL REGISTRATIONISRCTN, ISRCTN16912075. Registered 6th April 2020, http://www.isrctn.com/ISRCTN16912075 FULL PROTOCOL: The full protocol (version 4.0, 29th May 2020) is attached as an additional file, accessible from the Trials website (Additional file 1). In the interest in expediting dissemination of this material, the familiar formatting has been eliminated; this Letter serves as a summary of the key elements of the full protocol. The study protocol has been reported in accordance with the Standard Protocol Items: Recommendations for Clinical Interventional Trials (SPIRIT) guidelines (Additional file 2).

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[Available online at this link](https://www.knowledgeshare.nhs.uk/index.php?PageID=link_resolver&link=ce2215fe587273aad403165e838f23b5)

1. **Vocal Cord Ulcer Following Endotracheal Intubation for Mechanical Ventilation in COVID-19 Pneumonia: A Case Report from Northern Italy.**  
   Bertone Fabio The American journal of case reports 2020;21:e928126.

BACKGROUND This report is of a case of vocal cord ulceration following endotracheal intubation and mechanical ventilation in a patient with severe COVID-19 pneumonia. CASE REPORT A 57-year-old woman was admitted to our hospital (Ospedale Degli Infermi, Biella, Italy) presenting with symptoms of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection. Reverse transcription real-time polymerase chain reaction from a nasopharyngeal swab, authorized and validated by the World Health Organization, confirmed the diagnosis of SARS-CoV-2 infection. The patient presented with severe respiratory distress and underwent orotracheal intubation for mechanical ventilation. She was extubated after 9 days in the intensive care unit. After extubation, the patient experienced an onset of dysphonia, and was evaluated by the otolaryngologist. The videolaryngoscopy revealed the presence of an ulceration at the level of the left vocal cord. Steroids and proton pump inhibitors were administered as primary therapy for 1 week. Two weeks later, a significant improvement in the patient's voice quality was observed. A second videolaryngoscopy was performed, which displayed healing of the ulcer at the level of the left vocal fold and rapid re-epithelialization. CONCLUSIONS This report has shown that with increasing numbers of cases of severe COVID-19 pneumonia requiring endotracheal intubation and mechanical ventilation, clinical guidelines should be followed to ensure that the incidence of complications such as vocal cord ulceration are as low as possible.

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Click on the Search button (illustrated with binoculars). This will open up a search window. Type in the term you need to find and links to all of the references to that term within the document will be displayed in the window. You can jump to each reference by clicking it.

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Select Edit from the menu, the Find and type in your term in the search box which is presented. The search function will locate the first use of the term in the document. By pressing 'next' you will jump to further references.

## B. Search History

|  | **Source** | **Criteria** | **Results** |
| --- | --- | --- | --- |
| 1. | Medline | ((extubation OR intubation) AND (post OR after OR following OR surviv\*)).ti,ab | 29633 |
| 2. | Medline | ("COVID-19" OR coronavirus OR "SARS-CoV-2" OR "severe acute respiratory syndrome coronavirus 2").ti,ab | 79778 |
| 3. | Medline | (1 AND 2) | 336 |
| 4. | Medline | (voice OR swallow\*).ti,ab | 60387 |
| 5. | Medline | (3 AND 4) | 5 |
| 6. | Medline | (extubation OR intubation).ti,ab | 55255 |
| 7. | Medline | (2 AND 4 AND 6) | 6 |
| 8. | EMBASE | ((extubation OR intubation) AND (post OR after OR following OR surviv\*)).ti,ab | 50388 |
| 9. | EMBASE | ("COVID-19" OR coronavirus OR "SARS-CoV-2" OR "severe acute respiratory syndrome coronavirus 2").ti,ab | 80074 |
| 10. | EMBASE | (8 AND 9) | 386 |
| 11. | EMBASE | (voice OR swallow\*).ti,ab | 85993 |
| 12. | EMBASE | (10 AND 11) | 6 |
| 13. | EMBASE | (extubation OR intubation).ti,ab | 83478 |
| 14. | EMBASE | (9 AND 11 AND 13) | 7 |
| 15. | CINAHL | ((extubation OR intubation) AND (post OR after OR following OR surviv\*)).ti,ab | 7683 |
| 16. | CINAHL | ("COVID-19" OR coronavirus OR "SARS-CoV-2" OR "severe acute respiratory syndrome coronavirus 2").ti,ab | 24204 |
| 17. | CINAHL | (15 AND 16) | 80 |
| 18. | CINAHL | (voice OR swallow\*).ti,ab | 30502 |
| 19. | CINAHL | (17 AND 18) | 3 |
| 20. | CINAHL | (extubation OR intubation).ti,ab | 16584 |
| 21. | CINAHL | (16 AND 18 AND 20) | 3 |
| 22. | EMCARE | ((extubation OR intubation) AND (post OR after OR following OR surviv\*)).ti,ab | 14695 |
| 23. | EMCARE | ("COVID-19" OR coronavirus OR "SARS-CoV-2" OR "severe acute respiratory syndrome coronavirus 2").ti,ab | 20837 |
| 24. | EMCARE | (22 AND 23) | 87 |
| 25. | EMCARE | (voice OR swallow\*).ti,ab | 29878 |
| 26. | EMCARE | (24 AND 25) | 0 |
| 27. | EMCARE | (extubation OR intubation).ti,ab | 26660 |
| 28. | EMCARE | (23 AND 25 AND 27) | 1 |
| 29. | AMED | ((extubation OR intubation) AND (post OR after OR following OR surviv\*)).ti,ab | 30 |
| 30. | AMED | ("COVID-19" OR coronavirus OR "SARS-CoV-2" OR "severe acute respiratory syndrome coronavirus 2").ti,ab | 13 |
| 31. | AMED | (29 AND 30) | 0 |
| 32. | AMED | (voice OR swallow\*).ti,ab | 1584 |
| 33. | AMED | (31 AND 32) | 0 |
| 34. | AMED | (extubation OR intubation).ti,ab | 143 |
| 35. | AMED | (30 AND 32 AND 34) | 0 |

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