Swallowing function before and after tracheal cannula removal.

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Primary objective:What is the incidence of an unsafe swallow situation (PAS score >= 6) after decannulation in ICU patients who had a safe swallow situation with a tracheal cannula prior to decannulation (PAS score < 6)?Secondary objective:-...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON57435

Source
ToetsingOnline

Brief title
Swallowing function before and after tracheal cannula removal.

Condition

- Other condition

Synonym
dysphagia, swallowing disorder

Health condition

dysfagie tijdens Intensive Care opname

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Financiering vanuit onderscheidend gebied van het ziekenhuis

Intervention

Keyword: Dysphagia, swallowing function, tracheal cannula, weaning of mechanical ventilation

Outcome measures

Primary outcome

How many patients during FEES 2 had a PAS score >= 6, who during FEES 1 had a

PAS score of 6 or

Secondary outcome

- Change in PAS score between FEES 1 (with trachea cannula in) and FEES 2?

(after decannulation)

- Trachea cannula reinsertion after FEES 2.

- Dietary prescription based on IDSSI after FEES 1 and dietary prescription

based on IDDSI after FEES 2.

Study description

Background summary

During an Intensive Care admission, a large proportion of patients receive invasive ventilation via an endotracheal tube. If severe muscle weakness has developed during treatment, resulting in a long withdrawal period, a tracheal cannula is often chosen for patient comfort. The IC-MCL aims to assess <24h after percutaneous tracheal cannula placement whether speaking during ventilation is possible.
As soon as a patient speaks during ventilation, the speech therapist is consulted. At the time the cuff is emptied, the patient is able to undergo swallow training because laryngeal lift is then better compared with a full

cuff. (Ding R et al., 2005)
Dysphagia in ICU patients with tracheotomy is common: 3% - 62%. (Zuercher P et al., 2019) Our own research also shows that on the 1st day of practice, 93% of ICU patients with a tracheotomy have an NPO diet using the International Dysphagia Diet Standardisation Initiative (IDDSI) (Cichero JA et al., 2017). A Flexible Endoscopic Evaluation of Swallowing (FEES) is the gold standard to objectify swallowing function. (Jaghbeer M et al., 2023) During a FEES, the following observation points are included: velo-pharyngeal closure, tongue base activity, pharyngeal contraction, sensibility, salivation and laryngeal function. These points lead to a Penetration Aspiration Score (PAS) (Rosenbek et al,. 1996)
In the current protocol, the tracheal cannula is removed when the patient is no longer dependent on ventilation. Positive pressure under the vocal cords is important for safe swallowing function (Brendan McGrath et al., 2016) During withdrawal from ventilation and swallow training with empty cuff, pressure under the vocal cords is maintained by positive end-expiratory pressure (PEEP) from the ventilator. Because of this positive pressure, sensibility in the oral pharynx is better than without pressure. (Skoretz S et al., 2020) From my own observations, it is suspected that swallowing function is reduced after decanulation, leading to a risk of aspiration and penetration of food. However, this has not been studied in a structured manner. To objectify safe swallowing during a FEES, the PAS score is used. (6)
1. Ding R, Logemann JA. Swallow physiology in patients with trach cuff inflated or deflated: a retrospective study. Head Neck. 2005 Sep;27(9):809-13. doi: 10.1002/hed.20248. PMID: 16086414.
2. Zuercher P, Moret CS, Dziewas R, Schefold JC. Dysphagia in the intensive care unit: epidemiology, mechanisms, and clinical management. Crit Care. 2019 Mar 28;23(1):103. doi: 10.1186/s13054-019-2400-2. PMID: 30922363; PMCID: PMC6438038.
3. Jaghbeer M, Sutt AL, Bergström L. Dysphagia Management and Cervical Auscultation: Reliability and Validity Against FEES. Dysphagia. 2023 Feb;38(1):305-8
4. Brendan McGrath et al. ACV: a novel technique for communication in the ventilator-dependent tracheostomy patient. Journal Intensive Care Society. 2016 Feb;17(1):19-26. Doi: 10.1177/1751143715607549.
5. Skoretz S, Anger N, Wellman L, et al. A systematic review of tracheostomy modifications and swallowing in adults. Dysphagia 2020;35:935-47.
6 Rosebek et al, a penetration aspiration scale. Dysphagia. 2016 March (11) 93-98.

Study objective

Primary objective:
What is the incidence of an unsafe swallow situation (PAS score >= 6) after decannulation in ICU patients who had a safe swallow situation with a tracheal cannula prior to decannulation (PAS score < 6)?

Secondary objective:
- Is there a change in swallowing function measured by the PAS-score during a FEES before and after decannulation?
- What is the rate of FEES-indicated reinsertion of the tracheal cannula?
- What is the FEES-indicated change in dietary prescription after decannulation.

Study design

Observational study.

Study burden and risks

- Coughing due to choking during FEES.
- Second FEES as aditional burden for the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients admitted to the ICU who have a trachea cannula due to prolonged withdrawal of ventilation and receive swallowing training from the speech therapist

Exclusion criteria

- contra indication deflation cuff .i.e. trachea obstruction
- Patients diagnosed with ALS or other progressive neuromuscular disease
- Not proficient in speaking and/or understanding Dutch.
- delirium
- patients with a tracheostomy (for example patients after total laryngeal extirpation)
- patients with oral feeding restrictions due to underlying medical conditions.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-02-2025
Enrollment:	54
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	22-04-2025
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL88431.099.24