

# **\*Does maintaining endotracheal tube cuff pressures at 20 mm Hg prevent dysphagia and hoarseness after anterior cervical spine surgery?\***

## **A randomised controlled trial.**

Published: 10-08-2011

Last updated: 19-03-2025

To determine if adjusting endotracheal tube cuff pressure after placement of a retractor during anterior cervical spine surgery prevents postoperative dysphagia. Furthermore laryngo-tracheal complaints (hoarseness and sore throat) will be scored.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Administration site reactions
<b>Study type</b>	Interventional

## **Summary**

### **ID**

NL-OMON39864

### **Source**

ToetsingOnline

### **Brief title**

-Endotracheal tube cuff pressures in anterior cervical spine surgery

### **Condition**

- Administration site reactions
- Procedural related injuries and complications NEC
- Upper respiratory tract disorders (excl infections)

### **Synonym**

dysphagia, problems with swallowing

### **Research involving**

Human

## Sponsors and support

**Primary sponsor:** Medisch Centrum Haaglanden

**Source(s) of monetary or material Support:** Wetenschapsfonds

## Intervention

**Keyword:** Anterior cervical spine surgery, Dysphagia, Endotracheal tube cuff pressure, Hoarseness

## Outcome measures

### Primary outcome

Postoperative dysphagia

### Secondary outcome

Postoperative sore throat and hoarseness.

## Study description

### Background summary

In anterior cervical spine surgery a retractor is used. Previous studies showed an increase of endotracheal tube cuff pressures after placement of a retractor. It is known that a high endotracheal tube cuff pressure increases the incidence of postoperative dysphagia, hoarseness, and sore throat. However, until now no evidence supports maintaining the endotracheal tube cuff pressure during anterior cervical spine surgery to prevent this comorbidity.

### Study objective

To determine if adjusting endotracheal tube cuff pressure after placement of a retractor during anterior cervical spine surgery prevents postoperative dysphagia. Furthermore laryngo-tracheal complaints (hoarseness and sore throat) will be scored.

### Study design

Study patients are randomized in two arms. In the control arm endotracheal tube cuff pressure is not adjusted after retractor placement. In the intervention

arm endotracheal tube cuff pressure after retractor placement is maintained at 20 mm Hg. Twenty-four hours and 2 months after the operation the study patients are questioned about dysphagia, hoarseness and sore throat.

## **Intervention**

Maintaining the endotracheal tube cuff pressure to 20 mm Hg after retractor placement

## **Study burden and risks**

The study patient will be interviewed postoperative. Maintaining the endotracheal tube cuff pressure does not imply extra risks of burden to the study patient .

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Male and non-pregnant female patients between 18-90 years of age requiring anterior cervical spine surgery on 1 or more levels with the use of a retractor

## Exclusion criteria

Pre-operative dysphagia, hoarseness, sore throat or recurrent laryngeal nerve palsy

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

**Primary purpose:** Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2012
Enrollment:	177
Type:	Actual

### Medical products/devices used

Generic name:	cuff pressure gauge
Registration:	Yes - CE intended use

## Ethics review

Approved WMO

Date: 10-08-2011  
Application type: First submission  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 08-11-2011  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 24-10-2014  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25072  
Source: NTR  
Title:

### In other registers

Register	ID
CCMO	NL35829.098.11
OMON	NL-OMON25072