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
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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Administration site reactions
Study type	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
Medisch Centrum Haaglanden

Lijnbaan 32
2501 CK 2501CK
NL
Scientific
Medisch Centrum Haaglanden

Lijnbaan 32
2501 CK 2501CK
NL

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: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL35829.098.11
OMON	NL-OMON25072