‘Does maintaining endotracheal tube cuff pressures at 20 mm Hg prevent dysphagia and hoarseness after anterior cervical spine surgery?’
A randomised controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25072

Source
Nationaal Trial Register

Health condition

Dysphagia, hoarseness, anterior cervical spine surgery, endotracheal tube cuff pressures, sore throat

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Medisch Centrum Haaglanden

Intervention

Outcome measures

Primary outcome

Postoperative dysphagia. This will be scored with the Bazaz dysphagia scale twenty-four

hours and 2 months after the operation.

Secondary outcome

Postoperative sore throat, postoperative hoarseness and length of stay.

Sore throat and hoarseness will be scored twenty-four hours and 2 months after the operation. Hoarseness will be scored using a clinician-based voice assessment protocol; Grade, Roughness, Breathiness, Asthenia, Strain (GRBAS) and by using a numeric rating scale (NRS). A sore throat will be recorded using a NRS.

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 a sore throat. However, until now no evidence supports maintaining the endotracheal tube cuff pressure during anterior cervical spine surgery to prevent this comorbidity.

Our objective is 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 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 study patients are questioned about dysphagia, hoarseness and sore throat.

One hundred seventy-seven study patients aged 18-90 years scheduled for anterior cervical spine surgery on 1 or more levels with the use of a retractor will be randomized.

In the control arm no endotracheal tube cuff pressure intervention is performed after retractor application. In the intervention arm the endotracheal tube cuff pressure is maintained at 20 mm Hg after placement and after removal of the retractor. Main study parameters/ end points are postoperative dysphagia, sore throat and hoarseness.

Study objective

Incidence of post-operative sore dysphagia, sore throat and hoarseness in patients getting anterior cervical spine surgery is not influenced by correction of tube cuff pressure to 20 mm

Hg (normal value) after placement of a retractor in the operation wound.

Study design

N/A

Intervention

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 during the length of the operation.

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Eligibility criteria

Inclusion criteria

1. Patients requiring primary anterior cervical spine surgery with the use of a retractor;

2. Male and non-pregnant female patients between 18-90 years of age;

3. Patients who signed the Ethics Committee approved specific Informed Consent Form prior to surgery.

Exclusion criteria

1. Pre-operative dysphagia, sore throat or hoarseness;

2. Pre-operative recurrent laryngeal nerve palsy;

3. Dutch language not mastered;

4. Planned fiberoptic intubation or rapid sequence induction;

5. Peroperative use of N2O;

6. Mentally disabled patients.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-01-2012
Enrollment:	164
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-07-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39864
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3400
NTR-old	NTR3542
CCMO	NL35829.098.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39864

Study results

Summary results
N/A