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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25072

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Medisch Centrum Haaglanden
Overige ondersteuning: Medisch Centrum Haaglanden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative dysphagia. This will be scored with the Bazaz dysphagia scale twenty-four hours and 2 months after the operation.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-01-2012
Aantal proefpersonen:	164
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-07-2012

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39864
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A