Vocal cord pathology after short term intubation.

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Long-term and crash intubations have adverse effects on the vocal folds. After short term endotracheal intubation (less than 3 hours) hoarseness complaints do exist, but its effect on the vocal folds is unknown. We aim to investigate the incidence...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27083

Bron
Nationaal Trial Register

Aandoening

Primary Objective: is there any vocal fold pathology after short term intubation?
Secondary Objectives:
- Which vocal fold pathology occurs after short term intubation?
- What is the effect of short term intubation on voice quality?
- What are the subjective findings of the patients regarding their voice after short term intubation?

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre
P/O Box 5800, 6202 AZ Maastricht
Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Vocal fold pathology documented by videolaryngostroboscopy, voice analysis and validated questionnaires.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Long-term and crash intubations have adverse effects on the vocal folds. After short term endotracheal intubation (less than 3 hours) hoarseness complaints do exist, but its effect on the vocal folds is unknown. We aim to investigate the incidence and severity of vocal fold pathology after short term intubation.

Objective:

Primary Objective: Is there any vocal fold pathology after short term intubation?

Secondary Objectives:

1. Which vocal fold pathology occurs after short term intubation?

2. What is the effect of short term intubation on voice quality?

3. What are the subjective findings of the patients regarding their voice after short term intubation?

Study design:

We propose to perform a structured, prospective observational study to document the existence of vocal fold pathology and to categorize vocal fold pathology after short term intubation and to ask patients about their voice quality after short term intubation.

Based on the findings of this study, future studies can be designed aimed at optimizing intubation techniques, devices and material.

Study population:

Adult patients, planned for elective surgery under general anaesthesia requiring endotracheal or laryngeal mask intubation.

Intervention:

Short term intubation evaluated by videolaryngostroboscopy, voice analysis, validated questionnaires.

Main study parameters/endpoints:

Vocal fold pathology documented by videolaryngostroboscopy, voice analysis and validated questionnaires.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Participants will be asked to complete the Voice Handicap Index (VHI) pre- and post-operatively, this takes approximately 10 minutes.

A videolaryngostroboscopy is performed pre- and post-operatively. With a rigid 90 degree endoscope the vocal folds are monitored via the mouth while the participant is making an [i]-like sound. Seldom a retching feeling occurs during this test. Vomiting is very rare.
The participants will undergo an acoustic analysis of the voice whereby a microphone is attached to the head which does not provide any discomfort.

Doel van het onderzoek

Long-term and crash intubations have adverse effects on the vocal folds. After short term endotracheal intubation (less than 3 hours) hoarseness complaints do exist, but its effect on the vocal folds is unknown. We aim to investigate the incidence and severity of vocal fold pathology after short term intubation.

Onderzoeksopzet

1. Day 0: Data collection;

2. Day 1: Data collection;

3. Day 15-42: Data collection.

Onderzoeksproduct en/of interventie

1. Videolaryngostroboscopy;

2. Acoustic analysis;

3. Voice Handicap Index (questionnaire).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All adult (>18years) patients, male and female undergoing an elective procedure under general anaesthesia requiring endotracheal intubation or laryngeal mask ventilation. Short term is defined as lasting less than 3 hours.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Upper airway and neck operations, procedures after which the view on the larynx is hindered;

2. Procedures taking more than 3 hours.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	18-10-2010
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-10-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34031
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2440
NTR-old	NTR2549
CCMO	NL33665.068.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34031

Resultaten

Samenvatting resultaten
N/A