

Vocal cord pathology after short term intubation

Published: 08-11-2010

Last updated: 19-03-2025

First objective; to document the existence and to categorize vocal fold pathology after short term intubation and to study voice related patient complaints after short term intubation. Second and third objective; to study the pattern/type of injury...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON34031

Source

ToetsingOnline

Brief title

Vocal cord pathology after intubation

Condition

- Other condition
- Procedural related injuries and complications NEC

Synonym

vocal cord disorders

Health condition

stemklachten

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: intubation, pathology, vocal cords

Outcome measures

Primary outcome

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

Secondary outcome

not applicable

Study description

Background summary

Long-term and crash intubations have adverse effects on the vocal folds. After short term intubations hoarseness complaints do exist shortly after detubation, but its effects on the vocal folds are unknown. We aim to investigate the incidence and severity of vocal fold pathology after short term intubation.

Study objective

First objective; to document the existence and to categorize vocal fold pathology after short term intubation and to study voice related patient complaints after short term intubation.

Second and third objective; to study the pattern/type of injury and to identify possible risk factors. To investigate the relationship between post-operative hoarseness and findings at videolaryngostroboscopy

Study design

We propose to perform a structured 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 burden and risks

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.

Contacts

Public

Medisch Universitair Ziekenhuis Maastricht

Postbus 5800

6202 AZ

NL

Scientific

Medisch Universitair Ziekenhuis Maastricht

Postbus 5800

6202 AZ

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

Upper airway and neck operations. Procedures after which view on the larynx is disabled. Procedures taking more than 3 hours.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 22-06-2011

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 08-11-2010

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 27083

Source: NTR

Title:

In other registers

Register	ID
Other	2549
CCMO	NL33665.068.10
OMON	NL-OMON27083