Bronchoscopy: Oral versus Nasal introduction

Published: 23-07-2014
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The aim of this study is to compare nasal and oral insertion and to determine which of them is more comfortable and less time consuming for the patient.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON41153

Source
ToetsingOnline

Brief title
BON-study

Condition

- Respiratory tract therapeutic procedures

Synonym
Bronchoscopy

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bronchoscopy, Nasal, Oral

Outcome measures

Primary outcome

Time needed until vocal cords have been passed.

Secondary outcome

Time needed until conversion, quality of life, VAS-painscore, total time of the

scopy, Borgscore for dyspnea and possible complications like nosebleeds.

Study description

Background summary

In order to perform a bronchoscopy, the bronchoscope can be inserted through the nose or mouth. Usually insertion through the nose is preferred, although both methods are commonly used in practise. A Korean study states that oral insertion is more comfortable for patients than nasal insertion, also less dyspnea was reported when oral insertion was used. The insertion route had no significant effect on the outcome. If this is also the case for other etnicities is not sure.

Nasal insertion is known to have a higher rate of nose bleeds and might be a more difficult insertion pathway. It is possible for the patient to experience more pain or discomfort when nasal insertion is used. On the other hand, an inserted mouthpiece will not be used while experienced dyspnea is lower, which might result in a more comfortable experience. If nasal insertion seems impossible, conversion to the oral route is justified after both nostrills have been tried for insertion. Oral insertion is accompanied with an extensive feeling of dyspnea and a feeling of retching. Also there is the fear of scope biting by patients, to prevent this from happening an mouthpiece is used. Chances for insertion bleeding and impossible insertion are much lower.

Hypothesis: Oral insertion for bronchoscopy is a faster and more comfortable route for the patient than nasal insertion.

Study objective

The aim of this study is to compare nasal and oral insertion and to determine which of them is more comfortable and less time consuming for the patient.

Study design

This study is a randomized controlled intervention study.

Intervention

Nasal or oral inserted bronchoscopy.

Study burden and risks

The patient will be asked to fill out a questionaire before and after bronchoscopy. During bronchoscopy there is no action required of the patient, the researcher observes the bronchoscopy. During bronchoscopy there is no other risk for the patient than risks for bronchoscopy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Indication for bronchoscopy;
Age > 18;
Compos mentis;
Control of Dutch language.

Exclusion criteria

Hemorrhagic diathesis;
Active use of bood thinners / anticoagulants (if ascal is stopped 7 days before bronchoscopy OR INR is +/- 1.5 with Vit. K antagonists inclusion is possible);
Recent ENT-surgery's (<4 weeks);
Recent asthma / COPD exacerbation/ respiratory tract infection (< 2 weeks);
Allergic rhinitis (unless treated or not within the season);
Gastro-oesophageal reflux disease (unless PPI control);
Non coorperative / sedated patient.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-07-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2014
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL48853.101.14