Decongestants for dilating the nasal cavity, a randomised, blinded, prospective study to prevent iatrogenic epistaxis during nasotracheal intubation

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Primary Objective:The purpose of this study is to investigate the clinical efficacy of xylomethazoline, combined with dilating the nasal passage way with a polyvinyl-alcohol nasal dilator in the prevention of iatrogenic epistaxis during nasotracheal…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON41173

Source
ToetsingOnline

Brief title
Nasal Intubation Study

Condition

- Procedural related injuries and complications NEC

Synonym
epistaxis, nasal trauma

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

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

Intervention

Keyword: dilation nasal cavity, epistaxis, mucosal damage, nasal intubation

Outcome measures

Primary outcome

• Severity of the epistaxis

• Requiring suction

• Navigability of the tube during nasal passage

Secondary outcome

• Number of attempts

• Resistance during intubation

• Difficulty of intubation (grade of intubation)

• Evaluation of nasal complications

• Persistent nasal bleeding

• Nasal pain (NRS-score)

• Nasal trauma

• Difficulty of nasal breathing

Study description

Background summary

Nasotracheal intubation is a frequently employed intubation technique for dental and ear nose and throat surgical procedures, but bears the risk for damage to nasal and pharyngeal mucosa. Passage of the tube through the nasal cavity may lacerate of the mucosa, dislocate conchae and even create a fausse route. The most common complication after nasotracheal intubation is epistaxis, which complicates intubation as well as the operation itself because of loss of

visability. Importantly, nasal trauma may also lead to considerable patient discomfort.

During the past 15 years, various methods, such as different tubes, guidewires or decongestiva and lubricants have been suggested in order to prevent trauma. Various studies assessed these methods to prove their efficacy. Many kinds of tubes have been evaluated: a more flexible tube, side-beveled tubes and warming the tube. The silicone tipped endotracheal tube seemed to be better in terms of navigability and less peri-operative nasal injury. Intranasal xylomethazoline 0,1% drops and lidocaine 2% jelly has been proved to reduce the incidence and severity of epistaxis after nasotracheal intubation in preschool children. Others found that the use of esophageal stethoscope-obturated ETT*s was effective, and comparable to thermosoftening, in preventing epistaxis associated with nasotracheal intubation. Despite all the above-mentioned preventive measures, trauma to the nasopharyngeal mucosa during nasal intubation is still common and in particular epistaxis is estimated to occur in 17-80% of the nasal intubations.

Study objective

Primary Objective:

The purpose of this study is to investigate the clinical efficacy of xylomethazoline, combined with dilating the nasal passage way with a polyvinyl-alcohol nasal dilator in the prevention of iatrogenic epistaxis during nasotracheal intubation.

Secondary Objective:

To investigate the clinical efficacy of xylomethazoline with a polyvinyl-alcohol nasal dilator to facilitate the nasal passage way of the nasotracheal tube during nasal intubation.

Study design

This study is a randomized controlled trial with non-invasive measurements. The study will be performed in the Catharina Hospital Eindhoven. Adult patients requiring nasal intubation are eligible and will be asked to participate in this study.
Patients will receive either a nasal decongestant (xylomethazoline) combined with a polyvinyl-alcohol nasal dilator 60 minutes before nasal intubation and xylomethazoline 5 minutes before the intubation (intervention group), or only a nasal decongestant xylomethazoline 5 minutes before the intubation (control group). The intubator will score the intubation characteristics and the severity of an eventual epistaxis and eventual nasal complications will be

graded. The study will end after discharge from the postoperative anesthesia care unit.

Intervention

Patients will receive either a nasal decongestant (xylomethazoline) combined with a polyvinyl-alcohol nasal dilator 60 minutes before nasal intubation and xylomethazoline 5 minutes before the intubation(intervention group)

Study burden and risks

Nasotracheal intubation is a frequently employed intubation technique, but passage of the tube through the nasal cavity may cause iatrogenic trauma. This iatrogenic trauma may complicate airway management as well as the operation itself. Furthermore, the procedure the patient may experience discomfort, epistaxis and nasal pain.
Patients in the intervention group will receive 60 minutes before the planned surgery xylomethazoline intranasally followed by a polyvinyl-alcohol (PVA) nasal dressing (Merocel®) in both nostrils. Anesthesia will be induced according to current standard of care. Xylomethazoline is current standard of care during nasotracheal intubation, and discomfort due to the nasal dilator will be minimal. The burden for the subject is very low and is in proportion, and justifies the proposed study. The intervention is possibly beneficial for the subject by reducing the risk for epistaxis and mucosal trauma.

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

o Age older than 18 years
o Nasal intubation indicated and required for the planned surgery
o Informed consent

Exclusion criteria

o Age less than 18 years old
o COPD Gold 3 or 4
o Severe dyspnoe
o (History of) nasal trauma or anatomical deformities
o Known allergy to any of the medications used

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-08-2014
Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	polyvinyl-alcohol nasal dilator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-07-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL48149.060.14