Decongestiva (neusontzwellers) voor het ontzwellen van de neusholte, om schade aan het neusslijmvlies en neusbloedingen bij intubatie door de neus te voorkomen

Gepubliceerd: 13-08-2014 Laatst bijgewerkt: 13-12-2022

Nasotracheal intubation is a frequently employed intubation technique, but passage of the tube through the nasal cavity may lacerate the mucosa, and create a fausse route. In the present study we therefore aim to evaluate whether a new strategy that...

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

Samenvatting

ID

NL-OMON20173

Bron
NTR

Aandoening

Epistaxis
Nasal intubation

Ondersteuning

Primaire sponsor: Catharina Ziekenhuis
Overige ondersteuning: Catharina Ziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

•Severity of the epistaxis:
o none/slight/moderate/severe
o requiring suction: yes/no
• Navigability of the tube during nasal passage (smooth or impinged)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Nasotracheal intubation is a frequently employed intubation technique, but passage of the tube through the nasal cavity may lacerate the mucosa, and create a fausse route. In the present study we therefore aim to evaluate whether a new strategy that combines application of a decongestivum in combination with dilation of the nasal cavity reduces nasal trauma during nasotracheal intubation. We hypothesize that preoperative application of xylomethazoline and polyvinyl-alcohol nasal dilator will facilitate nasotracheal intubation and reduce epistaxis after nasal intubation.
Objective: The main purpose of this study is to investigate the clinical efficacy of xylomethazoline, combined with dilating the nasal passage way with polyvinyl-alcohol nasal dilator in the prevention of iatrogenic epistaxis after nasotracheal intubation. The secondary objective is to investigate the clinical efficacy of xylomethazoline and with polyvinyl-alcohol nasal packaging to dilating the nasal passage way in the passage of the nasotracheal tube during nasal intubation.

Study design: This study is a randomized controlled trial with non-invasive measurements. It is a blinded, prospective study.

Study population: All adult (≥18 years old) patients requiring nasal intubation in Catharina Hospital Eindhoven are eligible to participate in this study. Patients with COPD Gold 3 or 4, severe dyspnoea, (history of) nasal trauma or anatomical deformities or known allergy to any of the medications used will be excluded.

Intervention: 60 minutes before the planned surgery the patient will receive xylomethazoline intranasally followed by a polyvinyl-alcohol (PVA) nasal dressing (Merocel®) as a mechanical dilator in both nostrils.

Standard care: xylometazoline will be applicated in both nostrils shortly (5 minutes) before the induction of anesthesia.
Main study parameters/endpoints: The main study parameters are the severity of epistaxis and the navigability of the nasal passage.

Doel van het onderzoek

Nasotracheal intubation is a frequently employed intubation technique, but passage of the tube through the nasal cavity may lacerate the mucosa, and create a fausse route. In the present study we therefore aim to evaluate whether a new strategy that combines application of a decongestivum in combination with dilation of the nasal cavity reduces nasal trauma during nasotracheal intubation. We hypothesize that preoperative application of xylomethazoline and polyvinyl-alcohol nasal dilator will facilitate nasotracheal intubation and reduce epistaxis after nasal intubation.

Onderzoeksopzet

- during nasal intubation

- after intubation

- during postoperative recovery the postoperative anesthesia care unit

Onderzoeksproduct en/of interventie

Patients in the intervention group will be prepared for anesthesia and surgery, according standard of care. 60 minutes before the planned surgery the patient will receive xylomethazoline intranasally followed by a polyvinyl-alcohol (PVA) nasal dressing (Merocel®) in both nostrils. Merocel PVA is sponge-like material consisting of highly biocompatible synthetic material that can be used as hemostatic agent. When hydrated the material expands and provides a tamponade effect by applying light surface pressure with minimal discomfort for the patient. By decongesting the mucosa with xylomethazoline in combination with Merocel® we expect that the nasal cavity will expand, which facilitates the passage of the nasal tube. We expect that by dilating the nasal cavity will ensure an mechanically easier and less traumatic intubation.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age older than 18 years

Nasal intubation indicated and required for the planned surgery

Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Age less than 18 years old

COPD Gold 3 or 4

Severe dyspnoe

(History of) nasal trauma or anatomical deformities

Known allergy to any of the medications used

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	18-08-2014
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4572
NTR-old	NTR4740
Ander register	NL4819.060.14 : ABR4819

Resultaten