

Trachospray Device for Airway Anesthesia

Gepubliceerd: 26-11-2019 Laatste bijgewerkt: 13-12-2022

The Trachospray device gives complete anesthesia of the airway

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

Samenvatting

ID

NL-OMON19975

Bron

NTR

Verkorte titel

Trachospray

Aandoening

N/A

Ondersteuning

Primaire sponsor: Radboud university medical center, Nijmegen, The Netherlands

Overige ondersteuning: The study is funded by the Radboudumc, Nijmegen, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Complete anesthesia of the airway as evaluated and demonstrated by awake laryngobronchoscopy with minimal discomfort for the subject.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Effective and fast topical anesthesia of the upper airway is of paramount importance in bronchoscopy, awake fiberoptic intubations and other instrumentations of the airway in order to avoid patient discomfort. Different methods of anesthetizing the airway have been described. Conventional topical airway anesthesia is not always effective due to non-optimal flow patterns and generation of ineffective local anesthetic aerosols. Other methods of anesthetizing the airway are more invasive.

In order to optimize topical anesthesia of the airway we constructed an fine mist spray device (Trachospray) for topical anesthesia of the airway, in which optimal airflow patterns are obtained and local anesthetic aerosols are generated which will reach the target zone for anesthetizing the airway.

Objective: In this study, the Trachospray device will be evaluated to see if complete anesthesia of the airway can be obtained, to evaluate its use and comfort level for the subjects while used during awake laryngobronchoscopy.

Study design: Interventional study.

Study population: 20 healthy human volunteers, ASA 1, 18-60 years old.

Intervention: Subjects will be asked to inhale 4 ml lidocaine 4% via the Trachospray device

Main study parameters/endpoints:

Complete anesthesia of the airway as evaluated and demonstrated by awake laryngobronchoscopy with minimal discomfort for the subject.

Nature and extent of the burden and risks associated with participation:

Inevitably there is some discomfort during the procedure, mainly airway irritation which causes coughing. Some post-procedural tracheal irritation and/or hoarseness and a dry mouth for 3 ± 4 h may occur.

Doel van het onderzoek

The Trachospray device gives complete anesthesia of the airway

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Subjects will be asked to inhale 4 ml lidocaine 4% via the Trachospray device

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age between 18-60 years
- ASA physical status 1

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Inability to cooperate with adequate airway assessment,
- History of hepatic, renal and coagulation diseases,
- Respiratory tract pathology
- Pregnancy
- Risk of regurgitation or aspiration
- Allergy to amide type of local anesthetics
- No written informed consent by subject

Onderzoekopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
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:	01-12-2019
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

N/A

Ethische beoordeling

Positief advies	
Datum:	26-11-2019
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	NL8187
Ander register	CMO regio Arnhem-Nijmegen : 2019-5755

Resultaten

Samenvatting resultaten

N/A