Soft Mist Spray Device for airway anaesthesia during awake videolaryngoscopy

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In this study, the Trachospray device will be evaluated with regard to blocking the airway reflexes during awake videolaryngoscopie.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON52115

Source
ToetsingOnline

Brief title
Evaluation Trachospray device for videolaryngoscopy

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
Airway anesthesia, Locoregional anesthesia of the airway

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Locoregional anesthesia airway, Videolaryngoscopy

Outcome measures

Primary outcome

Complete anesthesia of the airway as evaluated and demonstrated by awake

videolaryngoscopie with minimal

discomfort for the subject.

Secondary outcome

-

Study description

Background summary

Effective and fast topical anesthesia of the upper airway is of paramount importance in awake video laryngoscopy bronchoscopy, awake fiberoptic intubations and other instrumentations of the airway in order to avoid patient discomfort. Some patients have an (expected) difficult airway. It is very helpfull to be able to view the airway in advance, and possibly be able to secure the airway immediately before the patient is under general anesthesia and ventilation is necessary.

Different methods of anesthetizing the airway have been described. However, 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 an inhalation device (Trachospray) is constructed for topical anesthesia of the airway, in which more optimal airflow patterns are obtained and local anesthetic aerosols are generated which will reach the target zone for anesthetizing the airway.

Study objective

In this study, the Trachospray device will be evaluated with regard to blocking

the airway reflexes during awake videolaryngoscopie.

Study design

Prospective Interventional study

Intervention

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

Study burden and risks

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

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

Healthy ASA 1 patients between the age of 18 - 60 years old, with normal anatomy of the airways, and lean body weight of >50kg.

Exclusion criteria

Pregnancy, abnormal anatomy of the airways, allergy to amide type of local anesthetics

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):	26-08-2022
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Trachospray device;an local anesthetic aerosol generator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	21-04-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL78481.091.21