Trachospray Device for Airway Anesthesia

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19975

Source
NTR

Brief title
Trachospray

Health condition

N/A

Sponsors and support

Primary sponsor: Radboud university medical center, Nijmegen, The Netherlands
Source(s) of monetary or material Support: The study is funded by the Radboudumc, Nijmegen, The Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

The Trachospray device gives complete anesthesia of the airway

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	26-11-2019
Application type:	First submission

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
NTR-new	NL8187
Other	CMO regio Arnhem-Nijmegen : 2019-5755

Study results

Summary results
N/A