Soft Mist Nasal Administration Device for topical anaesthesia of the nasal cavity

Published: 28-08-2024
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In this study the NAA will be used for nasal topical anesthesia. We will evaluate complete anesthesia of the nasal mucosa for nasal instrumentation, the use of the NAA and the comfort level for the subjects.

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

Summary

ID

NL-OMON56973

Source
ToetsingOnline

Brief title
CT1 NAA

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
Locoregional anesthesia of the nasal cavity, Topical anesthesie

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, Medical device, Nasal cavity

Outcome measures

Primary outcome

Studying the level of anesthesia of the nasal mucosa as evaluated and

demonstrated with successful awake nasal instrumentation with minimal

discomfort for the subject.

Secondary outcome

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Study description

Background summary

Effective and fast topical anesthesia of the nasal mucosa is of paramount importance for nasal instrumentation like nasal fiberoptic procedures, awake nasal fiberoptic intubation and placement of nasogastric tubes. Conventional topical anesthesia for the nasal mucosa is often patchy and not always effective. We hypothesize that topical anesthesia of the nasal mucosa with the nasal atomizer adapter (NAA) provides good to excellent nasal topical anesthesia with high patient comfort.

Study objective

In this study the NAA will be used for nasal topical anesthesia. We will evaluate complete anesthesia of the nasal mucosa for nasal instrumentation, the use of the NAA and the comfort level for the subjects.

Study design

Interventional study.

Intervention

Lidocaine 4% will be applied intranasally with the NAA before nasal

instrumentation. On completion of the procedure the participant and the researcher will be asked to complete a feedback form.

Study burden and risks

Inevitably there is some discomfort during the procedure, mainly cause by nasal mucosa irritation. Some postprocedural
irritation for 3±4 h may occur.

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

- Age >18 years

- Lean body weight >= 50 kg
- ASA physical status 1 or 2

Exclusion criteria

• Inability to cooperate
• History of hepatic, renal and coagulation diseases,
• Respiratory tract pathology
• Obstruction of the nasal passage
• Chronic rhinitis
• Chronic sinusitis
• Pregnancy
• Allergy to amide type of local anaesthetics
• No written informed consent by subject

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-12-2024
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	NAA: nasal atomizer adapter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-08-2024
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	NL85958.091.23