

Perioperative decongestion and hemostasis, and postoperative analgesia for FESS after intranasal application of cocaine, tetracaine-oxymetazoline or ropivacaine-oxymetazoline

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Het bestuderen en vergelijken van cocaïne, tetracaïne-oxymetazoline en ropivacaïne-oxymetazoline wat betreft de peroperatieve decongestie en hemostasis en postoperatieve analgesie die zij bieden bij FESS. Study and compare the peroperative...

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

Summary

ID

NL-OMON32081

Source

ToetsingOnline

Brief title

Decongestion for FESS after application of intranasal medication

Condition

- Upper respiratory tract disorders (excl infections)
- Respiratory tract therapeutic procedures

Synonym

nasal polyposis, swollen mucous membrane of the nose

Research involving

Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis

Source(s) of monetary or material Support: onderzoeksstichting vakgroep anesthesie CWZ

Intervention

Keyword: decongestion, FESS, intranasal medication

Outcome measures

Primary outcome

The surgeon will range the operative site for decongestion and hemostasis using a numeric rating scale (NRS 0-10).

The peroperative bloodloss, the amount of extra ultracaine-epinefrine injections and the operation-time will be noted

Pain (+medication) nausea/vomiting (+medication), heartrate and bloodpressure, drowsiness and bloodloss will be registrated till 24 hours postoperatively (t=0,1 2, 6, 12, 18 and 24h)

Secondary outcome

Satisfaction of the patient about the treatment

Complications

Study description

Background summary

Before the start of a FESS-operation patients receive endonasal gauzes with cocaine, because of cocaines vasoconstrictive and analgetic qualities. However,

cocaine can have cardiotoxic side-effects.

Properly, an other topical medication can be equipotential for the vasoconstrictive and analgetic effect with less side-effects.

Study objective

Het bestuderen en vergelijken van cocaïne, tetracaïne-oxymetazoline en ropivacaïne-oxymetazoline wat betreft de peroperatieve decongestie en hemostasis en postoperatieve analgesie die zij bieden bij FESS.

Study and compare the peroperative decongestive and hemostatic effects and postoperative analgesia of cocaine, tetracain-oxymetazolin and ropivacain-oxymetazolin

Study design

Observational , double-blinded, randomised interventionstudie (pilot)

Intervention

The surgeon places intranasal gauzes with cocaine, ropivacaine-oxymetazolin or tetracaine-oxymetazolin during 15 minutes

Study burden and risks

Almost the entire treatment are routine-activities by FESS-operation.

The only extra intervention is placement of a second infuse during anesthesia.

A little hematoma can remain.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

First FESS-operation

Age: ≥ 18 years

ASA 1-3 (patient classification as by the American Society of Anesthesiology)

Competent and the Dutch language understanding in word and reading

Exclusion criteria

Perioperative intake anticoagulants

Chronic painsyndrom

Pregnancy

Allergy for lokal anesthetics

Psychiatric disorder with disease of reality experience

Study design

Design

| | |
|---------------------|-------------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-07-2008

Enrollment: 90

Type: Anticipated

Medical products/devices used

Product type: Medicine

Brand name: Cocaine

Generic name: Cocaine

Product type: Medicine

Brand name: Naropin

Generic name: Ropivacaine

Registration: Yes - NL outside intended use

Product type: Medicine

Brand name: Otrivin

Generic name: Oxymetazoline

Registration: Yes - NL intended use

Product type: Medicine

Brand name: Tetracaine

Generic name: Tetracaine

Registration: Yes - NL outside intended use

Ethics review

Approved WMO

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 |
|-----------------|------------------------|
| EudraCT | EUCTR2008-002020-29-NL |
| CCMO | NL23108.091.08 |