# 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 perooperative 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.
Proberly, an other topical medication can be equipotential for the vasocontrictive 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

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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: >=18years
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 |