

CO2-Lasertonsillotomy versus tonsillectomy in adults; a randomized multicentre study

No registrations found.

| | |
|------------------------------|------------------|
| Ethical review | Positive opinion |
| Status | Other |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON29298

Source

NTR

Brief title

TOMTOM-study

Health condition

tonsillitis, tonsillolithiasis, halitosis, dysphagia, OSAS (tonsilrelated),
chronisch/recidiverende tonsillitiden, tonsillolithiasis, halitosis, dysfagie, OSAS
(tonsilgerelateerd)

Sponsors and support

Primary sponsor: Hagaziekenhuis

LUMC

Viecuri

HMC

ZGT

RdG

MCL

JBZ

Gelderse Vallei

WZA

Amphia

Intervention

Outcome measures

Primary outcome

Number of postoperative recovery days until resumption of daily activities.

Secondary outcome

- Presence or absence of tonsil related complaint(s)
- Number of tonsillitis episodes per year
- Number of antibiotic treatment regimens required for tonsillitis (per year)
- Average number of sick days due to the tonsilrelated complaints (per year)
- Pain during / after the procedure (using VAS score)
- Duration of the procedure
- Patient satisfaction regarding the intervention and reduction of tonsilrelated complaints
- Resumption of daily activities (return to work / school resumption)
- Number of days absence from work / school
- Complications (short and long term)
- Budget impact of CO2-lasertonsillotomy versus cold dissection tonsillectomy
- Cost effectiveness (analysis) of CO2-lasertonsillotomy versus cold dissection tonsillectomy

Study description

Background summary

When conservative treatment fails in patients with tonsil related complaints, a tonsillectomy using the classical dissection technique can be performed.

In adults substantial morbidity following classical tonsillectomy under general anesthesia has been reported. An interesting alternative treatment for a specific selection of adult patients could be the CO2 lasertonsillotomy under local anesthesia in an outpatient clinical setting.

Several articles describe good treatment results and a decrease in perioperative and postoperative morbidity.

Our hypothesis is that CO2 lasertonsillotomy under local anesthesia is followed by a significantly shorter recovery period, that it is an effective treatment for tonsil related complaints and that it has better secondary outcome results compared to classical tonsillotomy

Study objective

Our hypothesis is that CO2 lasertonsillotomy under local anesthesia is followed by a significantly shorter recovery period, that it is an effective treatment for tonsil related complaints and that it has better secondary outcome results compared to classical tonsillotomy.

Study design

- pre-intervention
- 2 weeks post-intervention
- 6 weeks post-intervention
- 6 monts post-intervention
- 1 year post-intervention
- 2 year post-intervention

Intervention

- CO2-lasertonsillotomy under local anesthesia
- Cold dissection tonsillectomy

Contacts

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Eligibility criteria

Inclusion criteria

- age \geq 18 years
- tonsilrelated complaints with an indication for intervention
(chronic/rec. tonsillitis, tonsillolithiasis, halitosis, dysphagia, OSAS (tonsilrelated))

Exclusion criteria

- not cooperative / restless
- unable to open the mouth for a longer period
- history of peritonsillar abcess
- Friedman grade IV tonsils
- immunocompromised
- hemorrhagic diathesis / use of anticoagulants
- history of allergic reaction to local anesthetics
- in case of significant contra-indication for narcosis
- pregnancy
- extreme gag-reflex

Study design

Design

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

Recruitment

| | |
|---------------------------|------------|
| NL | |
| Recruitment status: | Other |
| Start date (anticipated): | 25-01-2018 |
| Enrollment: | 198 |
| Type: | Unknown |

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 25-02-2018 |
| Application type: | First submission |

Study registrations

Followed up by the following (possibly more current) registration

ID: 50550
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| NTR-new | NL6866 |
| NTR-old | NTR7044 |
| CCMO | NL57496.098.16 |
| OMON | NL-OMON50550 |

Study results