Tonsillectomy versus outpatient lasertonsillotomy in adult patients with tonsil related disease.

No registrations found.

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

Summary

ID

NL-OMON26334

Source
Nationaal Trial Register

Brief title
'SMOKE-protocol'

Health condition

tonsillotomy
carbondioxidelaser
lokal anesthesia
adults

tonsillotomie
carbondioxidelaser
lokale anesthesie
volwassenen

Sponsors and support

Primary sponsor: Maatschap KNO Haga Ziekenhuis / MC Haaglanden
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

Presence or absence of the complaints for which the patient has undergone surgery (chronic / recurrent tonsillitis, tonsillolithiasis, hallitosis).

Secondary outcome

1. Number of tonsillitis episodes per year objectified by their GP or ENT specialist;

2. Number of antibiotics associated with tonsillitis per year;

3. Average number of sick days per year due to the tonsil-related complaints;

4. Presence / absence of hallitosis;

5. Presence / absence of tonsillolithiasis;

6. Pain during / after the procedure (using VAS score);

7. Duration of the procedure;

8. Resumption of daily activities (return to work / school resumption);

9. Complications (short and long term);

10. Patient satisfaction.

Study description

Background summary

The purpose of this study is to demonstrate the effectiveness of treatment using the CO2-laser in one selected group of patients compared with a classical tonsillectomy. We also compare peri-operative en post-operative morbidity, pain, complications and patient satisfaction.

Study objective

When conservative treatment fail in patients with tonsil related complaints, a tonsillectomy

using the classical dissection technique van be performed. In adults substantial morbidity is reported following classical tonsillectomy under general anesthesia. An interesting alternative treatment for a specific selection of adult patients could be the CO2-lasertonsillotomy under local anethesia in an outpatient clinical setting. Several articles describe good treatment results and a decrease in perioperative and post-operative morbidity. Our hypothesis is that CO2-lasertonsillotomy is effective and there are better secondairy outcome results.

Study design

After an intake interview and randomisation, an appointment will be made for the intervention. The laser treatment is performed in the outpatient operating room, the traditional tonsillectomy in the operating room on an outpatient / short clinical stay. Two weeks after surgery, the patient is seen again to check the wound, then a questionnaire will also be taken. After 6 months, 1 and 2 years there will also be an evaluation and a questionnaire will be administered again. This is sent by email or taken by telephone. We also ask our patients to contact the clinic / researcher when tonsil related complaints exist during the study period.

Intervention

Study treament:

The CO2-lasertonsillotomies take place in our outpatient department that met the criteria for performing laser treatments. Patient will be instructed to take 1000 mg Paracetamol one hour prior to the procedure. Both the physician and the patient wear safety laser goggles and outside the room a warning lamp is clearly visible while the laser is in operation.

The patient is half lying. Subsequently, the superior, lateral and anterior parts of the tonsillar pillars will be infiltrated bilaterally with Xylocaine 2% and Adrenaline 1: 80,000. The F125 laser tube by Lumenis will be used with the laser in the continuous wave mode of operation and a beam diameter of 3 mm. Depending on the tonsil size, the power can be raised to 29 watts. With a tongue blade the tonsil will be presented and the tonsil surface is evaporated in a continuous sweeping motion. This act repeated layer by layer until a total cryptolysis occurred. The patient is instructed to hold his breath during activation of the laser and to exhale slowly after deactivation, to avoid inhaling the resulting smoke. On average a patient can hold his breath for 45 seconds (range 8-98 seconds). During the procedure the resulting smoke was continuously aspirated using a smoke evacuator. When a persistent local bleeding emerged, bipolar coagulation was used.

Control treatment:

The classical tonsillectomy will be planned in daycare or short clinical stay wich is possible in all participating centra. Before the operation patients get a peripheral infuse. In the operation room the patient recieves general anesthesia. The patient is placed in supine position after

which the patient is intubated. The mouth is opened using a mouth gag. An Alyss clip wil be attached to the superior pole of the tonsil. Then an incision is made through the anterior pillar of the tonsil to view the underlying tonsillar capsule. The incision is made close to the anterior fold and will be extended through the mucosa to the base of the tonsil. The space can be enlarged using scissors if necessary. Using a tonsil pliers the tonsil will be removed. Gauze are used to stop the bleeding. After 5 minutes we remove the guazes and check whether the wound is dry and, if necessary bleeding can be coagulated. The mouth gag is removed if the wound is dry. After surgery, the patient will be transported to the recovery and then to the day care unit . The anaesthesiologist will decide on post-operative pain medication / anti-emetics if necessary.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. Tonsilrelated complaints with an indication for intervention (chronic/rec. tonsillitis, tonsillolithiasis, hallitosis).

Exclusion criteria

1. Not cooperative / restless;

2. Unable to open the mouth for a longer period;

3. Presence of a strong gag reflex;

4. History of peritonsillar abcess;

5. Estimated duration of treatment > 30 min (based on tonsilsize and cooperation);

6. Immunocompromised;

7. Hemorrhagic diathesis;

8. Cardiac history.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-08-2011
Enrollment:	470
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-08-2011
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	NL2867
NTR-old	NTR3010
Other	METC Zuidwest Holland : 11-084
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A