Conventional tonsillectomy versus outpatient CO2-lasertonsillotomy in adult patients; a randomised controlled trial

Published: 29-07-2011
Last updated: 28-04-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON35754

Source
ToetsingOnline

Brief title
SMOKE protocol

Condition

- Head and neck therapeutic procedures

Synonym
recurrent tonsillitis, tonsil related complaints

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: maatschap KNO en ziekenhuis uit algemene middelen

Intervention

Keyword: adults, carbondioxidelaser, lokal anesthesia, tonsillotomy

Outcome measures

Primary outcome

Presence or absence of the complaints which the patient has undergone surgery

(chronic / recurrent tonsillitis, tonsillolithiasis, hallitosis).

- Number of tonsillitis episodes per year objectified by their GP or ENT

specialist

- Number of antibiotics associated with tonsillitis per year

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

- Presence / absence of hallitosis

- Presence / absence of tonsillolithiasis

Secondary outcome

- Pain during / after the procedure (using VAS score)

- Duration of the procedure

- Resumption of daily activities (return to work / school resumption)

- Complications (short and long term)

- Patient satisfaction

Study description

Background summary

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 objective

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 design

Unblinded randomnised controlled trial. The patient will tickets for a classic or a CO2 lasertonsillotomie tonsillectomy after informed consent. The draw will be done using a block-randomization in every participating hospital. That means that in each hospital closed envelopes will be used in which the treatment the patient will undergo is documentated. In every hospital 50% of the cases will recieve a traditional surgery and 50% a laser treatment. This ensures that the two treatments will be equally divided after inclusion of all hospitals, regardless of the number of patients in each participating hospital. We want a to demonstrate a difference in the percentage of patients free of symptoms between the two treatment groups of 80% vs 90%. With a power of 80% and a 2-sided alpha of 5%, there are 196 patients needed in both treatment groups. We will take into account a loss of approximately 20%. Therefore we want a total of 235 patients per group included.
We expect in the secondary outcomes greater differences between the two treatment groups. The number of these patients to demonstrate greater differences will certainly be sufficent.

Intervention

One group will undergo CO2-lasertonsillotomy, the other group will undergo a classical tonsillectomy.

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 were 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.

Study burden and risks

Complications laser treatment:
- About 10% is not free of complaints and has so many complaints that they get a classical tonsillectomy after laser treatment
- In total, approximately 22% of patients undergo more than 1 laser treatment
- Wound infection
- Bleeding for which intervention is required (<1%)
- Allergic reaction to local anesthetic
- Side effects of local anesthesia (xylocaine 2% / adrenaline 1:80.000) as described in the leaflet

Complications classical tonsillectomy
- Bleeding for which intervention is required (+ - 1.4%)
- Wound infection
- General anesthesia complications

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

Exclusion criteria

- not cooperative / restless
- unable to open the mouth for a longer period
- presence of a strong gag reflex
- history of peritonsillar abcess
- estimated duration of treatment > 30 min (based on tonsilsize and cooperation)

- immunocompromised
- hemorrhagic diathesis
- cardiac history

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	470
Type:	Actual

Ethics review

Approved WMO

Date:	29-07-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL36092.098.11