CO2-lasertonsillotomy versus tonsillectomy in adult patients; a multicenter randomized controlled trial

Published: 06-09-2016
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The purpose of this study is to evaluate the added value of CO2-laser tonsillotomy for tonsil related diseases.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON50550

Source
ToetsingOnline

Brief title
TOMTOM-study

Condition

- Respiratory tract therapeutic procedures

Synonym
tonsilrelated diseases

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: uit de algemene middelen

Intervention

Keyword: carbondioxidelaser, local anesthesia, tonsillectomy, tonsillotomy

Outcome measures

Primary outcome

- Number of days after the intervention until resumption of daily activities

Secondary outcome

- Presence or absence of tonsil related complaint

- Number of tonsillitis episodes per year objectified by their general

practitioner or ENT specialist

- Number of antibiotic treatment regimens required for tonsillitis (per year)

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

- 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 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 post-operative morbidity. Our hypothesis is that CO2-lasertonsillotomy is followed by a

significantly shorter recovery period, effective as treatment for tonsil related complaints and has better secondary outcome results compared to, classical tonsillectomy.

Study objective

The purpose of this study is to evaluate the added value of CO2-laser tonsillotomy for tonsil related diseases.

Study design

Open multicenter randomized controlled trial. The patient will randomly be selected for either a classic tonsillectomy or a CO2-lasertonsillotomy. Per hospital block-randomization will be used. We want to prove a difference in days until resumption of daily activities of at least 3. The average recovery time after tonsillectomy is 10 days (SD 5). With a power of 90% and a two sided alpha of 5% we need 59 patients per treatment group. With a maximum expected drop-out of 40% we need to include a total of 198 patients.
As the difference in secondary outcomes between both treatment-groups is expected to be greater than the primary outcome, the previously calculated number of patients should be sufficient for assessment of these outcomes as well.

Intervention

One group will undergo CO2-lasertonsillotomy, the other group will undergo a classical tonsillectomy.
Study treatment
The CO2-lasertonsillotomies will be performed in our outpatient department which meets the criteria for performing laser treatments. Patient will be instructed to take 1000 mg paracetamol one hour prior to the procedure. The superior, middle and lower part of the tonsil will be infiltrated bilaterally with xylocaine 2% and adrenaline 1: 80,000. The CO2 laser will be equipped with a F125 laser tube (Lumenis) and set in continuous wave mode with a 3mm laser beam. Depending on tonsil-size, the power will be set to a maximum of 29 watts. After presenting the tonsil with a tongue blade the surface of the tonsil will be evaporated in a continuous sweeping motion repeatedly until total cryptolysis has been accomplished and the tonsillar capsule has been reached. The patient is instructed to take a deep breath before activation of the laser and exhale slowly during the laser procedure to minimize doctor*s loss of vision due to intra oral smoke accumulation. After deactivation of the laser the patient should exhale residual breath before taking a first breath. During the procedure there will be continuous suction of the smoke. When a persistent local bleeding emerges, bipolar coagulation will be used.

Control treatment
The classical tonsillectomy will be planned in daycare or short clinical stay in one of the participating centers. Before the operation patients get a drip. In the operation room the patient receives general anesthesia. The patient is placed in supine position after intubation. The mouth is opened using a mouth gag. An Alyss clip will be attached to the superior pole of the tonsil after which 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 up to the base of the tonsil. Using a tonsil plier the tonsil will be removed. Gauzes are used to stop the bleeding. After 5 minutes the gauzes are removed and if necessary persistent bleeding will be stopped using electro-coagulation. The anesthesiologist will decide on post-operative pain medication / anti-emetics if necessary.

Study burden and risks

Complications of lasertonsillotomy
- 10% of patients is not free of primary complaint(s) and requires a subsequent classical tonsillectomy
- In total, approximately 22% of patients undergo more than 1 laser treatment
- Wound infection (+- 3-4%)
- 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 (+- 2-5%)
- 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, halitosis, dysphagia, OSAS (tonsilrelated))

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 tonsil size and cooperation)
- immunocompromised
- hemorrhagic diathesis
- cardiac history
- history of allergic reaction to local anesthetics

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):	22-01-2018
Enrollment:	198
Type:	Actual

Ethics review

Approved WMO

Date:	06-09-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	20-02-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO
Date: 29-09-2017

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 09-01-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 11-06-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 28-06-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 06-03-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 13-04-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29298
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL57496.098.16
OMON	NL-OMON29298