

A study of Thulium "RevoLix" laser usage for surgery to remove the tonsils

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| Submission date 23/03/2020 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 25/03/2020 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 09/01/2023 | Condition category Respiratory | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Recurrent or chronic inflammation of the tonsils (tonsillitis) is currently a global public health issue which can severely impair an individual's quality of life.

Tonsillectomy is a 3000-year-old operation. Tonsillectomy is a surgical procedure to remove the tonsils. Tonsils are two small glands located in the back of your throat. Although tonsillectomy is performed less often than it once was, it is still among the most common surgical procedures performed in children anywhere in the world. The main indication of tonsillectomy is the recurrent throat infection. Tonsillitis and the need for tonsillectomies are more common in children than adults. However, people of any age can experience trouble with their tonsils and require surgery.

There are several different ways to remove tonsils. Most common method is called "cold knife (steel) dissection." In this case, your surgeon removes your tonsils with a scalpel. Another common method for tonsillectomy involves burning away the tissues through a process called cauterization, CO2 laser etc. However, like with other surgeries, there are some risks with this procedure: swelling, intraoperational and postoperational bleeding, postoperational pain and delayed healing. Tonsillectomy with Thulium RevoLix laser usage could minimize the listed risks and thus improve the patient's quality of life after tonsillectomy surgery, as it is surgical laser available for soft tissue surgery which unifies all advantageous properties of existing laser principles in a single unit.

Who can participate?

Adults over 18 years with chronic or recurrent tonsillitis

What does the study involve?

Patients due to have tonsils removed surgically will have the right side tonsils removed using the Thulium RevoLix laser and the left side with the cold steel method. Patients will be followed up for 10 days to assess the difference between the two methods.

What are the possible benefits and risks of participating?

Improved quality of life: Having the tonsils removed, as an adult, can help prevent a recurring sore throat, or tonsillitis (inflammation of the tonsils), that may force you to miss work. By having the tonsils removed, patients should no longer experience uncomfortable symptoms,

such as pain and a sore throat related to tonsillitis

Fewer infections: As the tonsils will be removed and general health improved, those who experience tonsillitis caused by bacteria should have fewer infections.

Less use of medication: If patients have fewer tonsillitis infections, they may be prescribed less medication, such as antibiotics. Although antibiotics have many benefits, they kill off good bacteria as well as the bad.

There is no specific risk of operation regarding the technique of the operation. There are standard risks of operation tonsillectomy:

Reactions to anesthetics. Swelling, bleeding during surgery, bleeding during healing, infection.

Where is the study run from?

"Heratsi" #1 Hospital complex (Armenia)

When is the study starting and how long is it expected to run for?

May 2020 to November 2020 (updated 10/07/2020, previously: June 2020)

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A pilot study of Thulium RevoLix laser usage for tonsillectomy

Study objectives
The usage of Thulium laser for tonsillectomy could minimise intraoperational and postoperational hemorrhage, postoperational pain and swallowing difficulties, wound recovering period, compared with cold steel tonsillectomy method.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 19/03/2020, The Ethics Committee of Yerevan State Medical University named after Mkhitar Heratsi (2 Koryun str., Yerevan, Armenia 0025; (+374)77 919111 ;ec@ysmu.am), ref: N 6-1/ 2020

Study design

Interventional non-randomized pilot study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Recurrent or chronic tonsillitis

Interventions

Patient recruitment

Informed consent signing

All necessary diagnostics examination performing (blood analysis, urine analysis, chest XR, ECG)

Anesthesiologists examination

The right side tonsillectomy of all patients is performed with Thulium Revolix laser and the left side with cold steel tonsillectomy method

Hospital stay 2-4 days

Outpatient follow-up 12 days

End of participation from 13th postop day

Intervention Type

Procedure/Surgery

Primary outcome measure

Postoperative wound healing measured by assessment of wound surface recovery in post-operational period to 12th post-operational day

Secondary outcome measures

1. Intraoperative blood loss quantified by measuring suction bottle fluid and weight measurement of surgical sponges

2. Time taken for surgery will be measured from the beginning and finishing of each side tonsillectomy

3. Postoperative pain will be measured by a numerical rating scale from 0-10 at 2, 5, 7 and 10

post-operational days

4. Postoperative bleeding will be assessed by the effectiveness of management strategy (no therapy, clot suction, direct pressure or electrocautery) at 2, 5, 7 and 10 post-operational days

5. Time taken for complete healing measured by comparing both tonsillectomy sides by serial direct clinical examinations at 2, 5, 7 and 10 post-operational days

Overall study start date

03/02/2020

Completion date

01/11/2020

Eligibility

Key inclusion criteria

1. Chronic or recurrent tonsillitis
2. Age over 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

12

Key exclusion criteria

1. Bleeding diathesis
2. Poor anesthetic risk
3. Uncontrolled medical illness
4. Anemia
5. Acute infection

Date of first enrolment

01/05/2020

Date of final enrolment

01/06/2020

Locations

Countries of recruitment

Armenia

Study participating centre
"Heratsi" #1 Hospital Complex
Yerevan State Medical University
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
<http://www.hcplasticsurgery.com>

ROR
<https://ror.org/01vkzj587>

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Publication and dissemination of trial results are planned for June 2022. The researchers are intending to publish the results of the pilot study of comparative assessment of Thulium Revolix Laser usage for tonsillectomy in comparison with cold steel dissection with bipolar electrocautery.

Intention to publish date

01/06/2022

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|---------------------------------------|--------------|------------|----------------|-----------------|
| Preprint results | non-peer-reviewed results in preprint | 04/01/2023 | 09/01/2023 | No | No |