ISRCTN16280803 https://doi.org/10.1186/ISRCTN16280803

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

Submission date
23/03/2020

Recruitment status
No longer recruiting

Registration date
25/03/2020

Overall study status
Completed

Last Edited
09/01/2023

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 Thilium 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?
Prof. Anna Poghosyan (scientific)
anna.yu.poghosyan@gmail.com
Dr Manana Baghdasaryan (scientific)
m.baghdasaryan@yahoo.com
Dr Gurgen Mkhitaryan (scientific)
Mkhitaryan_GK@yahoo.com
Dr Vahe Vermishyan (public)
vahevermishyan@gmail.com
Dr Martin Misakyan (scientific)
misakyan86@inbox.ru

Contact information

Type(s)
Scientific

Contact name
Prof Anna Poghosyan

ORCID ID
https://orcid.org/0000-0002-5116-5644

Contact details
Yerevan State Medical University
2 Koryun str.
Yerevan
Armenia
0001
+374 91474169
anna.yu.poghosyan@gmail.com

Type(s)
Scientific

Contact name
Dr Manana Baghdasaryan

ORCID ID
https://orcid.org/0000-0003-1859-6685

Contact details
Yerevan State Medical University
2 Koryun str.
Yerevan
Armenia
0001
+374 91560125
m.baghdasaryan@yahoo.com

Type(s)
Scientific

Contact name
Dr Gurgen Mkhitaryan

ORCID ID
https://orcid.org/0000-0002-8616-1133

Contact details
Yerevan State Medical University
2 Koryun str.
Yerevan
Armenia
0014
+374 77300180
Mkhitaryan_GK@yahoo.com

Type(s)
Public

Contact name
Dr Vahe Vermishyan

ORCID ID
https://orcid.org/0000-0002-1745-4899

Contact details
Yerevan State Medical University
2 Koryun str.
Yerevan
Armenia
0050

+374 94661165
vahevermishyan@gmail.com

Type(s)
Scientific

Contact name
Dr Martin Misakyan

ORCID ID
https://orcid.org/0000-0001-9151-6181

Contact details
Yerevan State Medical University
2 Koryun str.
Yerevan
Armenia
0018
+374 96044054
misakyan86@inbox.ru

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Quality of life

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

Key secondary outcome(s))
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

Completion date
01/11/2020

Eligibility

Key inclusion criteria
1. Chronic or recurrent tonsillitis
2. Age over 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
60 Abovyan str.
Yerevan
Armenia
0025

Sponsor information

Organisation
Yerevan State Medical University

ROR
https://ror.org/01vkzj587

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results	non-peer-reviewed results in preprint	04/01/2023	09/01/2023	No	No