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Intracapsular tonsillectomy in the treatment of recurrent and chronic tonsillitis in adults : a protocol of a prospective, single-blinded, randomised study with a 5-year follow-up (the FINITE trial)

Piitulainen, Jaakko Matias

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# BMJ Open Intracapsular tonsillectomy in the treatment of recurrent and chronic tonsillitis in adults: a protocol of a prospective, single-blinded, randomised study with a 5-year follow-up (the FINITE trial)

Jaakko Matias Piitulainen <sup>1,2</sup>, Tapani Uusitalo,<sup>1,2</sup> Henrik M Sjöblom,<sup>1,2</sup> Lotta E Ivaska,<sup>1,2</sup> Henri Jegoroff,<sup>2</sup> Tommi Kauko,<sup>1</sup> Hannu Kokki,<sup>3</sup> Eero Kytö,<sup>1,2</sup> Iisa Mansikka,<sup>1,2</sup> Jenni Ylikoski,<sup>1,2</sup> Jussi Jero<sup>4</sup>

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For numbered affiliations see end of article.

## Correspondence to

Mr Jaakko Matias Piitulainen; [jiitu@utu.fi](mailto:jiitu@utu.fi)

## ABSTRACT

**Introduction** The standard surgical treatment for recurrent or chronic tonsillitis is extracapsular tonsillectomy. Recent studies show that intracapsular tonsillectomy has the potential to reduce the postoperative morbidity of patients undergoing tonsil surgery. The Finnish Intracapsular Tonsillectomy (FINITE) trial aims to provide level I evidence to support the hypothesis that the recovery time from tonsil surgery can be reduced with intracapsular tonsillectomy. Additionally, from this trial, major benefits in quality of life, reduction of postoperative complications, treatment costs and throat symptoms might be gained.

**Methods and analysis** The FINITE trial is a prospective, randomised, controlled, patient-blinded, three-arm clinical trial. It is designed to compare three different surgical methods being extracapsular monopolar tonsillectomy versus intracapsular microdebrider tonsillectomy versus intracapsular coblation tonsillectomy in the treatment of adult patients (16–65 years) suffering from recurrent or chronic tonsillitis. The study started in September 2019, and patients will be enrolled until a maximum of 200 patients are randomised. Currently, we are in the middle of the study with 125 patients enrolled as of 28 February 2022 and data collection is scheduled to be completed totally by December 2027. The primary endpoint of the study will be the recovery time from surgery. Secondary endpoints will be the postoperative pain scores and the use of analgesics during the first 3 weeks of recovery, postoperative haemorrhage, quality of life, tonsillar remnants, need for revision surgery, throat symptoms, treatment costs and sick leave. A follow-up by a questionnaire at 1–21 days and at 1, 6, 24 and 60 months will be conducted with a follow-up visit at the 6-month time point.

**Ethics and dissemination** Ethical approval was obtained from the Medical Ethics Committee of the Hospital District of Southwest Finland (reference number 29/1801/2019). Results will be made publicly available in peer-reviewed scientific journals.

**Trial registration number** NCT03654742.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is a prospective, randomised, controlled, patient-blinded, three-arm clinical trial.
- ⇒ Multiple standardised and validated questionnaires will be used during a 60-month follow-up period.
- ⇒ Two surgeons will perform the surgeries with different levels of experience, and the follow-up evaluators will be blinded to the surgery method.
- ⇒ Due to the sample size, the results will not likely show differences in post-tonsillectomy haemorrhage.
- ⇒ The difference in postoperative pain between groups may be limited because we aim to decrease the tonsil volume as much as possible.

## INTRODUCTION

Recurrent tonsillitis and chronic tonsillitis are the most common indications for tonsil surgery in adults.<sup>1</sup> Extracapsular tonsillectomy (ECTE) is the gold-standard operative procedure for recurrent tonsillitis and chronic tonsillitis. In the USA, 737 000 outpatient ECTEs are performed annually,<sup>2</sup> and in Finland, 7000–9000 annually.<sup>3</sup> However, ECTE causes substantial postoperative pain during the first 2 weeks after surgery<sup>4</sup> and includes a risk for primary and secondary haemorrhage.<sup>5</sup>

The operative management of recurrent tonsillitis and chronic tonsillitis remains controversial. For decades, it was thought that an extracapsular removal of the palatine tonsils is required for effective symptom alleviation in patients suffering from tonsillitis. To reduce morbidity after ECTE, various instrumentation is suggested to be used including CO<sub>2</sub>-laser,<sup>6</sup> coblation,<sup>7</sup> surgical

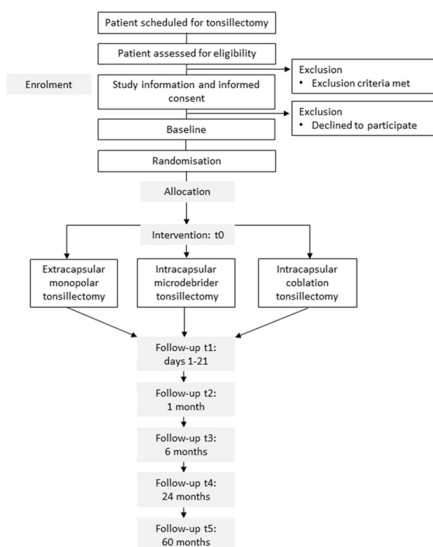
scissors, monopolar electrocautery, bipolar forceps and other instruments.<sup>8 9</sup> Tonsillotomy (TT) is a procedure for the partial removal of tonsils where only the protruding tonsillar tissue medial to the faucial pillars, which is approximately 50%–70% of the total tissue, is reduced.<sup>10</sup> Other studies have suggested removal of up to 90%–95% of tonsillar tissue, and this procedure is referred to as a type 2 TT or subtotal or intracapsular tonsillectomy (ICTE).<sup>11 12</sup> In both TT and ICTE, the aim is to remove tonsillar tissue without injuring the underlying pharyngeal muscles and without violating the tonsillar capsule.

Concerning children, both TT and ICTE result in a faster return to normal daily activity and a reduction in postoperative pain and haemorrhage requiring medical intervention.<sup>10 13 14</sup> Of course, these benefits need to be balanced against their clinical effectiveness.<sup>15</sup> In the paediatric population, both TT and ICTE have been established in the treatment of sleep breathing disorders.<sup>16 17</sup> Ericsson and Hultcrantz presented promising results after TT in adolescent patients with both recurrent tonsillitis and symptoms related to tonsil hypertrophy.<sup>18</sup>

In adults with tonsil-related symptoms, there are two systematic reviews that compare the postoperative morbidity and the effectiveness of ECTE to TT or ICTE in adults with tonsil-related symptoms.<sup>19 20</sup> To the best of our knowledge, seven randomised controlled trials (RCTs) have compared the postoperative morbidity between ECTE and TT or ICTE in the treatment of tonsil-related afflictions.<sup>14 18 21–27</sup> Compared with ECTE, TT and ICTE result in reduction of postoperative complications and a reduced use of analgesics in adults suffering from symptoms related to tonsillar hypertrophy. Two RCTs used the inclusion criteria of solely adults with recurrent tonsillitis or chronic tonsillitis<sup>21 22</sup> and were focused on comparing the effectiveness of ECTE and ICTE.

The rationale of this proposal and the evidence gap that it may fill are that this Finnish Intracapsular Tonsillectomy (FINITE) trial will compare three different surgical methods in a prospective setting: ECTE (monopolar), ICTE (coblation) and ICTE (microdebrider) in the treatment of adult patients suffering from recurrent tonsillitis or chronic tonsillitis. The overall objective of the study is to fill existing gaps in knowledge about the effectiveness of different tonsillectomies and provide level I evidence to support the hypothesis that the recovery time from tonsil surgery in adult patients with recurrent tonsillitis or chronic tonsillitis can be reduced with ICTE. Also, the complications, benefits and costs will be assessed.

The primary endpoint will be the recovery time from surgery. Recovery from surgery will be defined as resolution of pain on a Visual Analogue Scale (VAS 0–10) as pain <4 in rest and <6 on swallowing without regular use of analgesics. Secondary endpoints will be the postoperative pain scores and use of analgesics during the first 3 weeks of recovery, postoperative haemorrhage, quality of life, tonsillar remnants, need for revision surgery, throat symptoms, treatment costs and sick leave.



**Figure 1** Study design and flow of participants.

## METHODS AND ANALYSIS

### Trial design

The FINITE trial has been designed as a prospective, randomised, controlled, patient-blinded, three-arm clinical trial to compare extracapsular monopolar tonsillectomy versus intracapsular microdebrider tonsillectomy versus intracapsular coblation tonsillectomy in the treatment of recurrent tonsillitis and chronic tonsillitis in adults. The design of the trial is summarised in [figure 1](#) (see also [table 1](#) for an overview of the schedule). The trial is scheduled to be completed totally by December 2027.

### Participants

Patients aged 16–65 years and scheduled for tonsillectomy will be enrolled from the Turku University Hospital, Turku, Finland and Turunmaa Regional Hospital, Turku, Finland. The patient diagnosed with recurrent tonsillitis or chronic tonsillitis will be eligible for inclusion in the FINITE study. The study protocol will be described to eligible patients, and they will be invited to participate in the study. If they decide to participate, they will sign a written informed consent indicative of their approval. The inclusion of patients has been initiated in September 2019, and we have 125 enrolled as of early 2022.

### Inclusion criteria

The inclusion criteria will be an age between 16 and 65 years and planned tonsil surgery due to clinical indication as a diagnosis of either: recurrent tonsillitis, which is defined as at least three acute occurrences of tonsillitis in the last 12 months, or chronic tonsillitis, which is defined as a prolonged tonsil-derived throat pain and at least one symptom or sign indicating that symptoms are tonsil-related (ie, enlarged tonsils, tonsillar exudates, halitosis, tonsillar stones, enlarged and tender submandibular lymph nodes). In addition, these symptoms should affect the patient's daily activities and have lasted for at least 3 months. The diagnosis and treatment plans will be made

**Table 1** Study schedule

Time point	Study period						
	Enrolment -t1	Surgery t0: surgery	Postoperative course t1: days 1–21	t2: 1 month	t3: 6 months	t4: 24 months	t5: 60 months
Enrolment							
Eligibility	X						
Informed consent	X						
Randomisation	X						
Allocation	X						
Interventions							
Extracapsular monopolar tonsillectomy		X					
Intracapsular microdebrider tonsillectomy		X					
Intracapsular coblation tonsillectomy		X					
Assessments							
TOI-14	X				X	X	X
Perioperative data		X					
Brief Pain inventory			X				
NTSR 1 month				X			
NTSR 6, 24 and 60 months					X	X	X
GBI					X		
Clinical follow-up					X		
Sick leave					X	X	X
Case costs					X		X

NTSR, Nordic Tonsil Surgery Register; TOI-14, Tonsillectomy Outcome Inventory-14; GBI, Glasgow Benefit Inventory.

by an otorhinolaryngologist. All included patients will give written informed consent.

### Exclusion criteria

The exclusion criteria will be a peritonsillar abscess that occurred less than 1 month ago; an ongoing acute episode of tonsillitis; previous palatine tonsil surgery; a suspected tonsil malignancy; a high usage of anti-inflammatory analgesics, as defined by more than one defined daily dose during the previous 4 weeks, for example, >1.2 g ibuprofen/day or >500 mg naproxen/day; severe obstructive sleep apnoea or ongoing continuous positive airway pressure therapy; reflux-derived pharyngalgia; anticoagulant medication; any condition of haemophilia, pregnancy or lactation; and/or a current or positive history of a malignant disease with an ongoing active follow-up.

### Registration procedure

With their written informed consent, all patients will be registered into a common electronic database (Research Electronic Data Capture, REDCap 10.6.9 2021 Vanderbilt University, Nashville, Tennessee, USA) at the University of Turku.<sup>28</sup> The patients' names, electronic mail address, phone number, date of birth and sex will be registered along with clinical information and baseline severity of symptoms.

### Randomisation

Patients will be randomised with SAS (SAS 9.4, SAS Institute, Cary, North Carolina, USA) into permuted blocks of six patients. The randomisation will be performed in a 1:1:1 equal allocation ratio on the morning of or the day before surgery by the surgeon in the randomisation module of REDCap either to undergo extracapsular monopolar tonsillectomy, intracapsular microdebrider tonsillectomy or intracapsular coblation tonsillectomy.

### Blinding

The patients will remain unaware of their method of surgery until the 5-year follow-up is completed. The method of tonsil surgery will not be revealed in the hospital records. The clinical outcome at the 6-month follow-up visit will be evaluated by an otorhinolaryngologist (JMP, LEI, IM, EK, HMS and TU), who will be blinded to the surgery method. The patients will be scheduled to visit another otorhinolaryngologist than the surgeon who performed the operation. The data analysis will be performed by an experienced statistician (TK) to ensure the blinding of the principal investigator.

### Sample size calculation

Based on earlier study results, the average recovery time for ECTE is 12 days (SD=3).<sup>4</sup> If the recovery time for ICTE is 3 days shorter, we consider it as a clinically significant difference. In such a case, the effect size for a t-test is  $(12-9)/3=1$ . We aim to compare ICTE, in two groups, to ECTE. The level of significance is 5%, the Bonferroni correction is 2.5% and the desired power is 90%. When expecting a total of 20% dropouts, the sample size is 27

patients per group. However, if the SD is 4, the sample size is 55. We intend to use a sample size of 55 patients per group and a maximum of 200 patients will be enrolled. The main analyses will be based on the intention-to-treat principle, but both intention-to-treat and per-protocol analyses will be performed.

### Interventions

All surgeries will be performed by one of the two surgeons (TU and HMS), who both have experience in otorhinolaryngology with performing greater than 100 monopolar electrocautery tonsillectomies and TTs. Prior to starting, each study centre will establish a uniform operative technique. We consider the learning curve of ICTE to be 10 procedures for a surgeon who has a routine skill level in TT and ECTE.<sup>29</sup> The surgeons will perform their duties at a 70:30 ratio.

The surgical field in all techniques will be prepared with a tonsillectomy mouth gag. A pharyngeal round gaze sponge in saline solution will be used to prevent potential haemorrhage into the trachea. Velotraction with a suction catheter will be established for controlling the soft palate and especially the uvula. Intratonsillar injection of 1–2 millilitres of lidocaine-adrenaline will be administered for local haemostasis. The base of tongue will be left intact. Haemostasis is primarily achieved with compression with round gaze sponges soaked in lidocaine-adrenaline. When needed, small vessels will be coagulated. More profound vessels are, rarely, ligated to reduce the thermal effect to the operative area. After haemostasis, the surgical field will be photographed with a smart phone for later reference, and the tonsil remnants will be noted.

### Extracapsular monopolar tonsillectomy (control group)

A monopolar diathermy unit with 15-Watts power and spray settings will be used with a pen electrode and a blunt-needle tip. The tonsil will be grasped and pulled medially with forceps. Tonsillectomy will be performed by dissection in the peritonsillar plane. Parts of the upper and lateral palatal mucosal arches will be incised, and an extracapsular dissection for complete tonsil excision will be performed.

### Intracapsular microdebrider tonsillectomy

The recommended settings of 1500 rounds-per-minute for a microdebrider ('Straightshot M4 handpiece,' '12 degrees curved Tonsil blade' and 'Integrated Power Console', Medtronic, Minneapolis, Minnesota, USA) are used. Approximately 95% of the tonsillar tissue will be removed from an inferior to superior and from a posterior to anterior direction. The tonsil capsule will not be breached.

### Intracapsular coblation tonsillectomy

Approximately 95% of the tonsillar tissue will be removed with a coblation wand ('Procise EZ' or 'Evac 70 extra' Coblator II base unit, Smith & Nephew plc, Watford, UK). Power settings will be set to default and may be adjusted if needed. The tonsil capsule will not be breached.

## Patient and public involvement

Patients will fill a semistructured questionnaire 1 month after tonsil surgery regarding how their expectations were met. Their experience about the preoperative information will be analysed to detect any potential for improvement.

## OUTCOME PARAMETERS

### The primary endpoint

The primary endpoint of this trial is postoperative recovery time, which is defined as VAS pain, from 0 to 10 with <4 at rest and <6 on swallowing without regular use of analgesics. The regular use of analgesics is defined as a daily intake of two tablets of naproxen 500 mg and three or more tablets of tramadol-paracetamol 37.5/325 mg.

For the primary study endpoint, the duration of the postoperative recovery will be dependent on three endpoints: pain at rest, pain on swallowing and the regular use of analgesics. The patients will be advised for a daily use of analgesics for the first postoperative week to ensure analgesia use in all treatment arms.<sup>30</sup> The primary endpoint data will be collected within the 1–21 days time frame.

### Secondary endpoints

The secondary endpoints will be the postoperative pain scores (VAS 0–10) and postoperative use of analgesics at 1–21 days, early and late postoperative haemorrhage requiring a medical intervention at 1 month, detection of tonsil remnants at 6 months, life quality assessment at 6, 24 and 60 months, need for revision surgery at 6, 24 and 60 months, throat symptoms at 6, 24 and 60 months, sick leave needed at 6, 24 and 60 months, and treatment costs at 6 and 60 months.

### Data collection

The trial consists of an intervention treatment, through tonsil surgery, with a 60-month follow-up. As shown in [table 1](#), data will be collected before the surgery, perioperatively, 1–21 days after surgery, and 1, 6, 24 and 60 months after surgery. Data collection from all patients participating in the trial will include the baseline severity of symptoms, perioperative data and follow-up data. The perioperative data will be recorded using a report form ([table 2](#)).

### Follow-up

#### Assessment of postoperative recovery, pain and complications

Patients will use the Brief Pain Inventory (BPI) questionnaire in REDCap to record postoperative pain VAS scores, use of analgesics, nightly awakenings due to pain and return to normal daily activities 1–21 days after tonsil surgery. The Finnish version of the form has been adapted from an earlier study.<sup>4</sup> One month after surgery, patients will fill out the Nordic Tonsil Surgery Register, 1-month questionnaire (NTSR 1 month) to report the following outcomes: occurrence of postoperative haemorrhage, the occurrence of an infection within 1 month, the need for

a course of antibiotics, whether the patient contacted the healthcare system due to pain, in how many days after the surgery did the pain disappear, and in how many days after surgery did the patient resume his/her normal diet.<sup>31</sup>

### Assessment of tonsil remnants, quality of life and patient satisfaction

Patients will record data preoperatively and 6, 24 and 60 months after tonsil surgery with the Tonsillectomy Outcome Inventory-14 (TOI-14) questionnaire, a disease-specific, quality-of-life instrument for throat-related symptoms. The total score can range between 0 (no problems) and 100 (most severe problems) and in patients with recurrent or chronic tonsillitis, a score of about 20.0 indicates mild symptoms, 30.0 indicates moderate symptoms, and 40.0 or higher intense symptoms. The minimum significant change is 10.0 points. In a healthy population, the score is, in most cases, under 15.0, which is, in this study, used as a threshold score for significant efficacy (ie, when a patient is cured). The questionnaire has been validated into the Finnish language.<sup>32</sup> The Glasgow Benefit Inventory (GBI) is widely used in otorhinolaryngology to measure the change in quality of life associated with a surgical or pharmaceutical intervention. The individual responses are scored and added together to obtain a total score from –100 (worst outcome) to 0 (no change) to +100 (best outcome). A Finnish version of the questionnaire has been validated.<sup>33</sup> Patients will fill the GBI questionnaire 6 months after surgery. The NTSR questionnaire (NTSR 6, 24 and 60 months) collects data on whether the symptoms have alleviated after surgery and also whether the patient has experienced other symptoms.<sup>31</sup> In addition, patients will report the number of days on sick leave due to throat symptoms.

A clinical follow-up visit at 6 months after tonsil surgery will be performed by an otorhinolaryngologist (JMP, LEI, IM, EK, HMS and TU). Data will be collected with a standardised report form ([table 3](#)).

### Statistical analysis plan

The principal investigator (JMP) will collect the study data, and it will be analysed by an experienced biostatistician (TK). All efficacy and safety variables and primary and secondary outcome variables will be listed and tabulated by time points and summarised using descriptive statistics. Both the absolute measured values and the change from baseline will be recorded. Reasons for discontinuations will be tabulated in detail. Analyses of outcome variables will be performed using generalised linear models. Model fit is evaluated by examining residuals. All results will be presented with 95% CIs and p values. In a separate Statistical Analysis Plan (SAP), a more detailed view of the statistical analysis setup and its variables are presented. All analyses, tabulations, listings and figures will be conducted using R V.4.0.3 or later (R Core Team).

**Table 2** Template for data collection during hospitalisation (finite trial)

Preoperative	Intervention	Postoperative
Medical history of gastro-oesophageal reflux disease, smoking, peritonsillar abscess	Technique and quantity used for haemostasis	Postoperative haemorrhage before release from ward (yes, no)
No of courses of antibiotics for tonsillitis within 12 months	Problems related to haemostasis (yes, no)	Question used to ensure successful blinding of staff and patient: Was the surgical method used TE or ICTE?
No of acute episodes of tonsillitis within 12 months	Blood loss, estimated (millilitres)	
Planned for day surgery or overnight stay	Time from insertion to removal of mouth gag including velotraction, intratonsillar infiltration, surgery, haemostasis and photography of surgical area (minutes)	
Photograph of tonsils and tonsil grading using Brodsky Scale 1–4	Subjective estimated amount of residual tonsil tissue (0%–100%)	
Indication for surgery (recurrent or chronic tonsillitis)	Subjective perceived difficulty level of operation (0%–100%)	
Planned with adenoidectomy or not	Subjective perceived pleasantness of operation (0%–100%)	
No of sick leave days due to throat symptoms during previous 12 months		
ICTE, intracapsular tonsillectomy; TE, tonsillectomy.		

**Table 3** Structured reporting template for the 6-month follow-up visit (finite trial)

Photograph of surgical area	Yes or no
Tonsil remnants present?	Yes or no
Tonsillitis symptoms during last 6 months?	Yes or no
If yes, how many times?	
Specific symptoms present?	
Change in taste	Yes or no
Sensations of strictures or something extra in throat	Yes or no
Symptoms of velopharyngeal insufficiency	Yes or no
Painful swallowing (if yes; average on scale 0–10, 0=no pain, 10=most pain)	Yes or no
Has the patient contacted healthcare due to throat symptoms?	Yes or no
If yes, how many times?	
Question used to ensure successful blinding of the patient.	
The surgical method used was:	TE or ICTE
Question used to ensure successful blinding of the otorhinolaryngologist.	TE or ICTE (microdebrider) or ICTE (coblation)
The surgical method used was:	
ICTE, intracapsular tonsillectomy; TE, tonsillectomy.	

### Cost–benefit analysis and cost-effectiveness analysis

All tonsil surgery related direct medical costs will be estimated based on the actual input terms of resource use and personnel. Data of the costs will be provided by Auria Clinical Informatics from the information system of the Hospital District of Southwest Finland or determined in cooperation with the hospital administration. Operation time will be recorded in the case report forms. Indirect costs will arise from losses in productivity. These will be assessed by the BPI, in which the patient records when they consider themselves able to resume their normal daily activities, such as their work or studies after tonsil surgery. During the long-term follow-up, the patient will report at time points of 6, 24 and 60 months the number of sick leave days due to persistent throat symptoms.

A cost-effectiveness analysis will be performed to compare the relative costs and outcomes between ECTE and ICTE, in terms of reduced symptoms measured with TOI-14 and benefit in quality of life measured with GBI.

### Safety monitoring

Adverse events are defined as any undesirable experience occurring to a subject during a clinical trial whether or not these events are considered related to the investigational intervention. All adverse events reported by the patient, observed by the investigator, or the staff will be recorded. An interim analysis to ensure the safety of the ICTE will be performed after randomising 50–60 patients. We expect a 1% reoperation rate in all treatment groups.

### Data collection and confidentiality

The researchers have created an online database where all patients evaluated for the study enrolment will be recorded after a written informed consent is obtained. REDCap is used as the online platform. All data will be

handled confidentially, and the information in the datasets is non-identifiable. Data are gathered during hospitalisation, from clinical observations of the follow-up examination and from questionnaires filled in by the study patients. The information recorded from the non-participating patients will be used as data for a register-based study. The principal investigator (JMP) will be in charge of the common database with full access to the data. The access to the data is otherwise strictly limited. The online database will not be used for other purposes during the trial, and all of the visits to the database will be recorded in the database log. In order to prevent selection bias, we designed the study protocol to record data on all patients evaluated for eligibility.

### Withdrawal

During the enrolment, patients will be informed of their right to withdraw from the study without explanation at any time.

### Ethics and dissemination plan

The present protocol and applied informed consent forms were approved by the Medical Ethics Committee of the Hospital District of Southwest Finland. The trial will be conducted with the principles enunciated in the Declaration of Helsinki. Prior to randomisation and surgery, all patients participating in the study will give a written informed consent.

The results of this trial will be disseminated by publication in international peer-reviewed scientific journals and by presentations at international and domestic conferences.

### DISCUSSION

The hypothesis of the FINITE trial is that adult patients with recurrent or chronic tonsillitis can be treated



effectively with ICTE with a faster recovery time and less morbidity compared with ECTE. This hypothesis is supported by previous randomised studies.<sup>14 21 22 25 27</sup> Recurrent and chronic tonsillitis affects quality of life.<sup>34</sup> In adults, ECTE reduces episodes of tonsillitis and sore throat compared with conservative treatment.<sup>33</sup> The quality of life, 6 months after ECTE, is improved in adult patients with recurrent tonsillitis.<sup>35</sup> However, the benefits must be balanced against the risks of the surgery, notably post-intervention haemorrhage and a painful recovery.

If this study can demonstrate the faster recovery time of ICTE, the need for any prolonged absence from work, studies, or other activities would substantially decrease.

### Choice of the primary outcome

The definition of recovery time can vary. In addition to measuring pain, tools to assess interference of pain with functional recovery should be used.<sup>36</sup> We defined the duration of the postoperative recovery to be dependent on three endpoints: pain at rest, pain on swallowing and the regular use of analgesics.

The recovery after ECTE, lasting an average of 12–14 days, is associated with moderate to severe pain, even with adequate pain medication.<sup>4 37 38</sup> Tonsillectomy leaves an open wound in the pharynx, which heals per secundam. Most patients have significant pain, at rest with a VAS score >3 and during swallowing with a VAS score >5, during the first six mornings postoperatively even with analgesics. Without medication, most patients are willing to accept a pain level 3 at rest and 4 for dynamic pain.<sup>39</sup> Here, the threshold levels for recovery, being a VAS score <4 at rest and <6 on swallowing without the regular use of analgesics, are based on these earlier findings.

After TT, in the age group of 16–25 years, patients were able to return to their normal activity 4 days earlier compared with ECTE.<sup>18</sup> In three RCTs, adult patients were operated with ECTE on one tonsil and ICTE with coblation on the other tonsil.<sup>22 26 27</sup> Patients, after a 14-day follow-up, preferred the side that was performed with ICTE.<sup>22 26</sup>

Wilson *et al* compared ECTE with electrocautery vs ICTE with coblation or a microdebrider.<sup>14</sup> Patients (n=156, age=0.5–22 years) with obstruction were randomly assigned to three treatment groups. The return to normal nutrition and normal daily activity after ICTE was on average 2 days faster when compared with ECTE. This trial presented here is original and will help determine whether results of earlier studies can be applied to adult tonsillitis patients.

Based on the available information, most of the patients seem to recover within the first 21 postoperative days, and it is therefore reasonable to use this timeframe for the primary endpoint evaluation.

### Choice of the surgical instrumentation

In ECTE, there are no clinically relevant differences between different surgical instruments in terms of recovery time and pain scores.<sup>37 40</sup> Postoperative pain may

be slightly reduced by using cold instrumentation, such as with cold steel dissection, and by minimising thermal energy conducted to the wound bed when using electrocautery for dissection and/or coagulating small vessels.

In clinical practice, the advantages of the reduced operation time and the ease of achieving intraoperative haemostasis have led many surgeons to use electrocautery. In this study, we wanted to include the most common instruments for ECTE and ICTE in the USA.<sup>41</sup> Thus, ECTE is performed with monopolar dissection and ICTE with either a microdebrider or a coblation wand.

### Complications after tonsil surgery

Approximately 5%–15% of patients need a medical intervention for postoperative complications after ECTE, which notably include pain, haemorrhage, dehydration and poor nutrition.<sup>5</sup> The choice of the surgical method is an important factor regarding complications. The complication risk is known to be lower after TT<sup>11 31</sup> or ICTE.<sup>42</sup> In addition, a meticulous surgical technique is the key when trying to ease the postoperative recovery. Second, the choice of a surgical instrumentation, regardless of the extent of a surgery, may have an effect on the risk of postoperative haemorrhage. Cold instrumentation results in more primary haemorrhage and the use of electrocautery results in more secondary haemorrhage.<sup>43 44</sup>

### Recurrent symptoms, quality of life and tonsil remnants after tonsil surgery

Concerns have been raised regarding tonsillar remnants, which are always present after TT or ICTE and may, in theory, lead to persisting throat symptoms after operation.<sup>19</sup> With this prospect in mind, we aim to decrease tonsil volume as much as possible. A significant regrowth of tonsils in adults would be unexpected.<sup>23</sup>

In a short-term follow-up of adult patients randomly assigned to undergo either ICTE or ECTE, both surgery methods result in a significant reduction of symptoms of recurrent or chronic tonsillitis, and the ICTE group needed less pain medication.<sup>21</sup>

In this study, we will compare different surgical methods with an intention to reduce recovery time and postoperative complications. The presence of tonsil remnants (yes/no) both after the operation by the surgeon and at the 6-month follow-up by an otorhinolaryngologist will be documented. Throat symptoms, quality of life and need for reoperation at 6, 24 and 60 months will also be recorded. These secondary endpoints are essential in determining the potential of ICTE in the treatment of adult patients with recurrent or chronic tonsillitis.

### Direct and indirect costs to the public healthcare system

Tonsillitis and tonsil surgery place a substantial burden on healthcare resources.<sup>45</sup> The use of disposable instruments adds to the direct costs related to ICTE. On the other hand, differences between ICTE and ECTE related to the costs of instrumentation, operative time, use of analgesics, postoperative complications, reoperations and

loss of productivity may compensate for the expenses.<sup>46</sup> As part of this study, a cost–benefit analysis and a cost-effectiveness analysis will be conducted at 6-month and 5-year time points. We will consider both the direct and indirect costs related to ECTE and ICTE.

In summary, the FINITE trial is a prospective, randomised, three-arm clinical trial that compares extracapsular monopolar tonsillectomy with intracapsular microdebrider tonsillectomy and with intracapsular coblation tonsillectomy. The FINITE trial will provide new evidence to answer whether an ICTE provides a clinically significant reduction of recovery time after tonsil surgery in adults suffering from recurrent tonsillitis or chronic tonsillitis. Further, the different surgical methods will be evaluated in terms of primary and late complications, throat symptoms, tonsillar remnants, need for reoperation, quality of life, sick leave and treatment costs.

#### Author affiliations

<sup>1</sup>Department of Otorhinolaryngology – Head and Neck Surgery, Turku University Hospital, Turku, Finland

<sup>2</sup>Otorhinolaryngology, Faculty of Medicine, University of Turku, Turku, Finland

<sup>3</sup>School of Medicine, University of Eastern Finland, Joensuu, Finland

<sup>4</sup>Faculty of Medicine, University of Helsinki, Helsinki, Finland

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#### ORCID id

Jaakko Matias Piitulainen <http://orcid.org/0000-0001-9788-8904>

#### REFERENCES

- Hoddson EK, Gourin CG. Adult tonsillectomy: current indications and outcomes. *Otolaryngol Head Neck Surg* 2009;140:19–22.
- Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. *Natl Health Stat Report* 2009;11:1–25.
- Finnish Institute for Health and Welfare. Data Cubes - Periods of care with surgical procedures.. Available: [https://sampo.thl.fi/pivot/prod/fi/thil/perus01/fact\\_thil\\_perus01?row=operation\\_type-190964.197675.&column=time-6656#](https://sampo.thl.fi/pivot/prod/fi/thil/perus01/fact_thil_perus01?row=operation_type-190964.197675.&column=time-6656#) [Accessed 14 Jun 2021].
- Salonen A, Kokki H, Nuutinen J. Recovery after tonsillectomy in adults: a three-week follow-up study. *Laryngoscope* 2002;112:94–8.
- Tolska HK, Takala A, Pitkäniemi J, et al. Post-tonsillectomy haemorrhage more common than previously described—an institutional chart review. *Acta Otolaryngol* 2013;133:181–6.
- Hultcrantz E, Linder A, Markström A. Tonsillectomy or tonsillotomy?—A randomized study comparing postoperative pain and long-term effects. *Int J Pediatr Otorhinolaryngol* 1999;51:171–6.
- Timms MS, Temple RH. Coblation tonsillectomy: a double blind randomized controlled study. *J Laryngol Otol* 2002;116:450–2.
- Windfuhr JP, Werner JA. Tonsillotomy: it's time to clarify the facts. *Eur Arch Otorhinolaryngol* 2013;270:2985–96.
- Lee Y-C, Hsin L-J, Lin W-N, et al. Adolescents and adults undergoing temperature-controlled surgical instruments vs electrocautery in tonsillectomy: a systematic review and meta-analysis of randomized clinical trials. *JAMA Otolaryngol Head Neck Surg* 2020;146:339–46.
- Hultcrantz E, Ericsson E. Pediatric tonsillotomy with the radiofrequency technique: less morbidity and pain. *Laryngoscope* 2004;114:871–7.
- Windfuhr JP, Savva K, Dahm JD, et al. Tonsillotomy: facts and fiction. *Eur Arch Otorhinolaryngol* 2015;272:949–69.
- Koltai PJ, Solares CA, Mascha EJ, et al. Intracapsular partial tonsillectomy for tonsillar hypertrophy in children. *Laryngoscope* 2002;112:17–19.
- Sakki AJ, Mäkinen LK, Kanerva M, et al. Monopolar tonsillotomy versus cold dissection tonsillectomy in children: prospective study on postoperative recovery. *Int J Pediatr Otorhinolaryngol* 2021;141:110513.
- Wilson YL, Merer DM, Moscatello AL. Comparison of three common tonsillectomy techniques: a prospective randomized, double-blinded clinical study. *Laryngoscope* 2009;119:162–70.
- Blackshaw H, Springford LR, Zhang L-Y, et al. Tonsillectomy versus tonsillotomy for obstructive sleep-disordered breathing in children. *Cochrane Database Syst Rev* 2020;4:CD011365..
- Zhang L-Y, Zhong L, David M, et al. Tonsillectomy or tonsillotomy? A systematic review for paediatric sleep-disordered breathing. *Int J Pediatr Otorhinolaryngol* 2017;103:41–50.
- Smith S. Tonsillotomy: an alternative surgical option to total tonsillectomy in children with obstructive sleep apnoea. *Aust Fam Physician* 2016;45:894–6.
- Ericsson E, Hultcrantz E. Tonsil surgery in youths: good results with a less invasive method. *Laryngoscope* 2007;117:654–61.
- Wong Chung JERE, van Benthem PPG, Blom HM. Tonsillotomy versus tonsillectomy in adults suffering from tonsil-related afflictions: a systematic review. *Acta Otolaryngol* 2018;138:492–501.
- Amin N, Lakhani R. Intracapsular versus extracapsular dissection tonsillectomy for adults: a systematic review. *Laryngoscope* 2020;130:2325–35.
- Bender B, Blassnigg EC, Bechthold J, et al. Microdebrider-assisted intracapsular tonsillectomy in adults with chronic or recurrent tonsillitis. *Laryngoscope* 2015;125:2284–90.
- Kisser U, Lill C, Adderson-Kisser C, et al. Total versus subtotal tonsillectomy for recurrent tonsillitis - a prospective randomized noninferiority clinical trial. *Acta Otolaryngol* 2020;140:514–20.
- Wireklint S, Ericsson E. Health-Related quality of life after tonsillotomy versus tonsillectomy in young adults: 6 years postsurgery follow-up. *Eur Arch Otorhinolaryngol* 2012;269:1951–8.
- Ericsson E, Ledin T, Hultcrantz E. Long-Term improvement of quality of life as a result of tonsillotomy (with radiofrequency technique) and tonsillectomy in youths. *Laryngoscope* 2007;117:1272–9.
- Gaudreau PA, Gessler EM. Intracapsular tonsillectomy for keratosis pharyngeus: a pilot study of postoperative recovery and surgical efficacy. *Ear Nose Throat J* 2017;96:E6–9.
- Hall DJ, Littlefield PD, Birkmire-Peters DP, et al. Radiofrequency ablation versus electrocautery in tonsillectomy. *Otolaryngol Head Neck Surg* 2004;130:300–5.



- 27 Arya AK, Donne A, Nigam A. Double-Blind randomized controlled study of coblation tonsillotomy versus coblation tonsillectomy on postoperative pain in children. *Clin Otolaryngol* 2005;30:226–9.
- 28 Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
- 29 Carney AS, Harris PK, MacFarlane PL, et al. The coblation tonsillectomy learning curve. *Otolaryngol Head Neck Surg* 2008;138:149–52.
- 30 Aldamluji N, Burgess A, Pogatzki-Zahn E, et al. Prospect guideline for tonsillectomy: systematic review and procedure-specific postoperative pain management recommendations. *Anaesthesia* 2021;76:947–61.
- 31 Hallenstål N, Sunnergren O, Ericsson E, et al. Tonsil surgery in Sweden 2013–2015. indications, surgical methods and patient-reported outcomes from the National tonsil surgery register. *Acta Otolaryngol* 2017;137:1096–103.
- 32 Laajala A, Autio TJ, Ohtonen P, et al. Interpretation of tonsillectomy outcome Inventory-14 scores: a prospective matched cohort study. *Eur Arch Otorhinolaryngol* 2020;277:1499–505.
- 33 Koskenkorva T, Koivunen P, Koskela M, et al. Short-Term outcomes of tonsillectomy in adult patients with recurrent pharyngitis: a randomized controlled trial. *CMAJ* 2013;185:E331–6.
- 34 Burton MJ, Glasziou PP, Chong LY, et al. Tonsillectomy or adenotonsillectomy versus non-surgical treatment for chronic/recurrent acute tonsillitis. *Cochrane Database Syst Rev* 2014;334:CD001802.
- 35 Koskenkorva T, Koivunen P, Penna T, et al. Factors affecting quality-of-life impact of adult tonsillectomy. *J Laryngol Otol* 2009;123:1010–4.
- 36 Baamer RM, Iqbal A, Lobo DN, et al. Utility of unidimensional and functional pain assessment tools in adult postoperative patients: a systematic review. *Br J Anaesth* 2022;128:874–88.
- 37 Bäck L, Paloheimo M, Ylikoski J. Traditional tonsillectomy compared with bipolar radiofrequency thermal ablation tonsillectomy in adults: a pilot study. *Arch Otolaryngol Head Neck Surg* 2001;127:1106–12.
- 38 Magdy EA, Elwany S, el-Daly AS, et al. Coblation tonsillectomy: a prospective, double-blind, randomised, clinical and histopathological comparison with dissection-ligation, monopolar electrocautery and laser tonsillectomies. *J Laryngol Otol* 2008;122:282–90.
- 39 Lahtinen P, Kokki H, Hynynen M. Pain after cardiac surgery: a prospective cohort study of 1-year incidence and intensity. *Anesthesiology* 2006;105:794–800.
- 40 Pynnonen M, Brinkmeier JV, Thorne MC, et al. Coblation versus other surgical techniques for tonsillectomy. *Cochrane Database Syst Rev* 2017;8:CD004619.
- 41 Walner DL, Mularczyk C, Sweis A. utilization and trends in surgical instrument use in pediatric adenotonsillectomy. *International Journal of Pediatric Otorhinolaryngology* 2017;100:8–13.
- 42 Lee HS, Yoon HY, Jin HJ, et al. The safety and efficacy of powered intracapsular tonsillectomy in children: a meta-analysis. *Laryngoscope* 2018;128:732–44.
- 43 Lowe D, van der Meulen J, Cromwell D, David Lowe F, David Cromwell P, et al. Key messages from the National prospective tonsillectomy audit. *Laryngoscope* 2007;117:717–24.
- 44 Lundström F, Stafors J, Østvoll E, et al. Practice, complications and outcome in Swedish tonsil surgery 2009–2018. An observational longitudinal national cohort study. *Acta Otolaryngol* 2020;140:589–96.
- 45 Powell J, O'Hara J, Carrie S, et al. Is tonsillectomy recommended in adults with recurrent tonsillitis? *BMJ* 2017;357:j1450.
- 46 McCoy JL, Maguire RC, Tobey ABJ. Cost benefit of coblation versus electrocautery adenotonsillectomy for pediatric patients. *Int J Pediatr Otorhinolaryngol* 2020;136:110197.