CLINICAL TRIAL PROTOCOL

Multicenter, national, randomized, patient-blinded, parallel group, non-inferiority trial to compare tonsillotomy versus extracapsular tonsillectomy in adults with obstructive sleep apnea and tonsil hypertrophy: The TONOS Trial.

ClinicalTrials.gov NCT07580170

Version 23th January 2026

Clinical Trial Protocol

1. Administrative information

Title: Multicenter, national, randomized, patient-blinded, parallel group, non-inferiority trial to compare tonsillotomy versus extracapsular tonsillectomy in adults with obstructive sleep apnea and tonsil hypertrophy: The TONOS Trial.

Trial registration: Randomized clinical trial for tonsil surgery in adults with obstructive sleep apnea and enlarged tonsils (TONOS)

Structured summary:

Structured summary of trial design and methods, including items from the World Health Organization Trial Registration Data Set

Primary registry and trial identification number	ClinicalTrials.gov NCT07580170
Name of sponsor/company	Turku University Hospital
Contact for Public Queries	Jaakko Piitulainen
Contact for Scientific Queries	Jaakko Piitulainen
Public Title	Randomized clinical trial for tonsil surgery in adults with obstructive sleep apnea and enlarged tonsils (TONOS)
Scientific Title	Multicenter, national, randomized, parallel group, non-inferiority trial to compare tonsillotomy versus extracapsular tonsillectomy in adults with obstructive sleep apnea and tonsil hypertrophy: The TONOS Trial
Countries for Recruitment	Finland
Health Conditions Studied	Adult with obstructive sleep apnea and palatine tonsil hypertrophy
Interventions	Tonsillotomy versus extracapsular tonsillectomy
Key inclusion criteria	Age 18 – 65 years; Body Mass Index < 35; Tonsil size 2 – 4; Otherwise healthy patient fit for tonsil surgery; Indication for first line treatment for obstructive sleep apnea, defined as apnea-hypopnea index (AHI) > 15 and symptoms related to sleep apnea
Key exclusion criteria	Pathological hemostasis; Craniofacial deformities; Neurological condition with muscular hypotonia; Other surgical treatment for obstructive sleep apnea.
Study Type	Randomized, patient-blinded, parallel-group, non-inferiority trial
Date of First Enrollment (planned)	January 2025

Number of subjects	132
Primary outcomes	Between-group differences on the AHI, measured with home sleep study before surgery and 4-6, 24 and 60 months after surgery
Key Secondary Outcomes	Changes from baseline and 6, 12, 24 and 60 months after surgery in daytime sleepiness, measured with Epworth Sleepiness Scale (ESS). Changes in insomnia symptoms, measured with Insomnia Severity Index (ISI). Changes in quality of life, measured with General Health Questionnaire -12 (GHQ-12) and Depression Scale (DEPS). Surgical success rate, defined according to Sher's criteria: a reduction in AHI of >50% and a total AHI of <20 after surgery. Surgical cure rate, defined as a total AHI of <5 after surgery. Changes in nocturnal desaturation measured with oxygen saturation (SaO_2) mean, min, and SpO_2 <90% (T90) and ODI3, measured with home sleep study before surgery and 4-6, 24 and 60 months after surgery.
Ethics Review	VARHA/28047/13.02.02/2025
Individual Trial Participant Data sharing statement	Yes

Protocol version/date: Original protocol, 4.11.2025

Document	Date of Issue	Summary of Change
Original protocol	4.11.2025	Not applicable

Roles and responsibilities

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Contributors: JP and HS conceived of the study and developed the protocol, with input from JK, AL, SM, JR, IK, TK and UA. JP, HS and TK developed the statistical analyses plan.

Study coordinators: Registered ENT nurses Jaana Enroth and Sanna Turunen, Turku University Hospital

Coordinating center: The Department of Otorhinolaryngology – Head and Neck Surgery, Turku University Hospital.

Trial sponsor: This in an investigator-initiated trial. Funders of this trial do not participate or have any authority in design, conduct, analysis, and reporting of trial.

Trial Steering Committee: A steering committee is responsible for the design, integrity, and progress of the trial. The steering committee is also responsible for implementing any potential protocol modifications. The steering committee comprises staff of the Turku University Hospital and lead investigators of all participating study centers.

Trial Management Group: A trial management group is responsible for the day-to-day conduct of the trial.

Trial registration: The intended registry is ClinicalTrials.gov.

Protocol and statistical analysis plan: The original study protocol and statistical analysis plan are available in the ClinicalTrials.gov.

Data sharing: De-identified individual participant data may be shared in accordance with the EU General Data Protection Regulation (GDPR, Regulation (EU) 2016/679) and the Finnish Data Protection Act (Tietosuojalaki 1050/2018). Data may be shared upon reasonable request to the principal investigator to academic researchers whose research purpose is compatible with the informed consent provided by participants and approved by an ethics committee.

Funding: This is a non-industry-funded study. Financial support is sought from scientific or private foundations, or governmental or non-governmental organizations.

Conflicts of interest: No.

Dissemination policy: We will make results available nationally and internationally by presentations at local meetings, at national meetings (eg, Finnish Association of Otorhinolaryngology – Head and Neck Surgery) and international conferences, including the Confederation of European Otorhinolaryngology – Head and Neck Surgery as well as publications in leading journals to reach physicians treating obstructive sleep apnea more broadly. In the preparation of abstracts and publications, we will follow the criteria for authorship recommended by the International Committee of Medical Journal Editors (ICMJE); we do not intend to employ professional writers.

Public involvement: No patient or public involvement is planned.

Clinical Trial Protocol

Title

Multicenter, national, randomized, parallel-group, non-inferiority trial to compare tonsillotomy versus extracapsular tonsillectomy in adults with obstructive sleep apnea: The TONOS Protocol

Authors

Jaakko Piitulainen, Jenny Knubb, Ulla Anttalainen, Tommi Kauko, Ilpo Kinnunen, Aleksi Laajala, Saara Markkanen, Johanna Ruohoalho, Henrik Sjöblom

Background

Obstructive sleep apnea (OSA) is estimated to affect 3% of women and 10% of men 30 to 49 years of age in the United States [1]. The pathophysiology of OSA is attributed to the episodes of complete or partial obstruction of the airway during sleep, leading to oxygen desaturations and deterioration of sleep architecture [2]. Feeling unrefreshed by sleep, excessive daytime sleepiness, snoring, nocturnal gasping for air or choking are common symptoms reported by patients with OSA [3]. Non-specific symptoms such as insomnia, depression, fatigue, morning headaches and nightmares may be present [4].

The most important risk factor for OSA is obesity, followed by use of alcohol and tobacco, hypertension and diabetes mellitus [5]. Adenotonsillar hypertrophy, micrognathia, retrognathia and macroglossia are anatomical risk factors for OSA. These anatomical variations may exacerbate upper airway obstruction in velopharynx, oropharynx, tongue base or epiglottis during sleep [6].

The gold standard for diagnosis of OSA is a polysomnography in a clinical sleep laboratory. The clinical practice guideline of American Academy of Sleep Medicine (AASM) recommends polysomnography or home sleep apnea testing (HSAT) with a technically adequate device be used for the diagnosis of OSA [7]. Based on AASM criteria, the apnea-hypopnea index (AHI) is calculated. Traditionally, the AHI as a single parameter with cut points of 5, 15 and 30 have been used to indicate mild, moderate, and severe OSA, respectively. According recent reseach, oxygen desaturations and nocturnal hypoxemia relates better to daytime sleepiness and risk for cardiovascular diseases than AHI [8]. However, the treatment decision is a more complex process, including symptoms, age, and cardiometabolic comorbidities [9]. In the presence of OSA-related symptoms, there is a strong indication to treatment, irrespective of AHI [10].

Treatment options include positive airway pressure ventilation (CPAP), mandibular advancement therapy (MAD), weight reduction therapy in overweight patients, positional therapy, and upper airway surgery. The majority of patients experience a good symptom control and improved quality of sleep. Surgical options are tailored to fit the patient and treat the narrowing anatomical site of the upper airway. Clinical evaluation before upper airway surgery may be enhanced with the use of drug-induced sleep endoscopy (DISE) [11]. For patients with tonsillar hypertrophy, DISE is not recommended [12].

Extracapsular tonsillectomy (TE) alone is effective in adults with tonsillar hypertrophy and moderate-severe OSA [13], compared to modified uvulopharyngoplasty at 6 months [14]. A successful operative treatment outcome is predicted by larger tonsil size, younger age, and a lower body mass index [15–17].

Adult reviews suggest tonsillotomy (TT) reduces morbidity compared to TE [18,19]. In pediatric populations, the effectiveness of partial tonsil surgery for OSA is well-documented [20]. However, it remains unclear, whether TT is non-inferior to TE in adults in the treatment of OSA. To our knowledge, no head-to-head

adult trials comparing TE with TT using change in apnea-hypopnea index (ΔAHI), representing standard of care, as the primary endpoint. Thus, comparative efficacy on sleep outcomes in adults with OSA and tonsillar hypertrophy remains unknown.

Aim

To investigate whether TT is non-inferior compared to TE in treating OSA, by measuring home sleep study and validated questionnaires on quality of life, daytime sleepiness and insomnia.

Hypothesis

TT is non-inferior compared to TE in treating patients with moderate or severe OSA and grade 2 to 4 tonsil size.

Trial design

This trial is multicenter, national, randomized, parallel-group, non-inferiority trial. Participants are blinded to the allocated intervention with an allocation ratio 1:1.

Trial setting

Participants will be recruited from patients referred to an outpatient hospital clinic. The trial will be carried out in four tertiary hospitals in Finland.

Eligibility criteria

Inclusion criteria

Age 18 – 65 years; BMI < 35; Tonsil size 2 – 4; Otherwise healthy patient fit for tonsil surgery; Indication for first line treatment for obstructive sleep apnea, defined as: AHI > 15 and OSA symptoms.

Exclusion criteria

Pathological hemostasis or use of anticoagulation; Craniofacial deformities; Neurological condition with muscular hypotonia; Other surgical treatment for OSA.

Intervention and comparator

Tonsil surgery is performed while patient is under general anesthesia by experienced otorhinolaryngologist who are familiar with both techniques (a minimum of 20 procedures performed using each technique).

TT will be performed by removing approximately 60 - 90% of the tonsillar tissue, leaving a rim of tonsillar tissue on the tonsillar fossae. The tonsil capsule will not be breached.

TE 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.

The surgical instrumentation (eg. cold steel, monopolar diathermy with a pen electrode, bipolar scissors, coblation technique or a microdebrider) is selected by the surgeon.

Haemostasis is primarily achieved with compression with round gaze sponges soaked in saline. When needed, small vessels will be coagulated. If needed, gaze sponges soaked in lidocaine-adrenaline will be used.

Primary Outcome Measure

The primary outcome is changes in AHI at baseline and after surgery, measured with home sleep study 4-6, 24 and 60 months after surgery.

Secondary outcomes

The secondary outcomes are changes from baseline and 6, 12, 24 and 60 months after surgery in daytime sleepiness, measured with Epworth Sleepiness Scale (ESS); changes in insomnia symptoms, measured with Insomnia Severity Index (ISI); changes in quality of life, measured with General Health Questionnaire – 12 (GHQ-12) and Depression Scale (DEPS); Surgical success rate, defined according to Sher's criteria: a reduction in AHI of >50% and a total AHI of <20 after surgery; surgical cure rate, defined as a total AHI of <5 after surgery. Changes in nocturnal desaturation measured with oxygen saturation (SaO_2) mean, min, and SpO_2 <90% (T90) and Oxygen Desaturation Index at a 3% threshold (ODI3), measured with home sleep study before surgery and 4-6, 24 and 60 months after surgery.

Harms

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.

Participants are to be systematically assessed for postoperative hemorrhage, pain problem and infection, reported by participant with Nordic Tonsil Surgery Registry (NTSR) 30-day questionnaire; need for CPAP, MAD or other surgical intervention, measured by structured questionnaire 12, 24 and 60 months after tonsil surgery.

Participant timeline

Table 1: Study schedule of enrollment, interventions, and assessments.

	STUDY PERIOD							
	Enrollment		Post-randomization					
TIMEPOINT	$-t_1$ to 0	T_0: surgery	t_1: 30 days	t_2: 4-6 months	T_3: 6 months	T_4: 12 months	T_5: 24 months	T_6: 60 months
ENROLLMENT:								
Eligibility screen	X							
Informed consent	X							
Randomization		X						
INTERVENTION/ COMPARATOR:								
Tonsillotomy		X						
Extracapsular tonsillectomy		X						
ASSESSMENTS:								

Baseline home sleep study, patient characteristics, ESS, ISI, GHQ-12, DEPS	X							
NTSR 30 days			X					
Follow-up home sleep study				X				
ESS, ISI, GHQ-12, DEPS, NTSR 6 months					X			
Follow-up questionnaire 12 months, ESS, ISI, GHQ-12, DEPS, NTSR 12 months						X		
Follow-up questionnaire 24 months, ESS, ISI, GHQ-12, DEPS, NTSR 24 months							X	
Follow-up questionnaire 60 months, ESS, ISI, GHQ-12, DEPS, NTSR 60 months								X
Primary study center subgroup: Follow-up home sleep study							X	X
Primary study center subgroup: Clinical follow-up visit								X

Sample size

A power analysis was performed on August, 2025 for non-inferiority setup. Assuming a clinically relevant group difference to 10 events per hour in AHI (non-inferiority threshold) and with pooled standard deviation derived from literature for TE and from a previous study. Using the observed change in AHI from the aforementioned studies, the smaller difference in change revealed that 55 participants were needed in each group. Assuming 20% drop-out, the final sample size needed for this study is 132 participants total to achieve 80% statistical power in one-sided testing with 0.025 confidence level.

In detail, this is covered in the Statistical Analysis Plan.

Recruitment

Participants will be recruited from patients referred to the participating sites from primary care centers or private clinics. They should have symptoms of OSA and a home sleep study showing that their AHI was over 15, a body mass index less than 35 and a suspicion of tonsil hypertrophy. An information leaflet of the trial will be send to patients referred to a pulmonology clinic of the participating sites.

Inclusion and exclusion criteria will be verified at an outpatient visit, where a general otolaryngologic examination is performed by an ear-, nose- and throat (ENT) specialist. The size of the participant's tonsils will be graded. The information about the trial is provided. If the patient wishes to participate, a tonsil

surgery will be booked. If the previous home sleep study was conducted more than 12 months prior to enrolment, a new assessment is performed to determine the baseline. On the day of the surgery, participants will be randomized to receive either TE or TT. Follow-up home sleep study will be performed 4-6 months after the surgery and questionnaires measuring symptoms and quality of life will be performed 6, 12, 24 and 60 months after the surgery.

For participants recruited at the primary study site, a long-term follow-up is performed. Home sleep study is performed 2 and 5 years after the surgery, and a follow-up visit at the ENT department 5 years after the surgery

Randomization

Allocation sequence will be generated by an independent statistician with no involvement in evaluating or conducting the trial. Patients will be randomized with SAS (SAS 9.4, SAS Institute, Cary, North Carolina, USA) into permuted blocks of four patients. The randomization will be performed in a 1:1 equal allocation ratio on the morning of or the day before surgery by the study nurse in the randomization module of REDCap either to undergo TE or TT. Patients with tonsil size 2 will be stratified in Group A, and those with tonsil size 3 or 4 will be stratified in Group B.

Blinding

Due to the nature of surgical intervention, surgeon and care providers in the operation theatre are not blinded to treatment allocation. Trial participants, outcome assessors, and data analysts are blinded. Blinded outcome assessment was prioritized to minimize detection and reporting bias, particularly for patient-reported secondary outcomes. The primary outcome is objectively measured. Participants will remain unaware of their method of surgery until the 60-month follow-up is completed. The method of tonsil surgery will not be revealed in the hospital records.

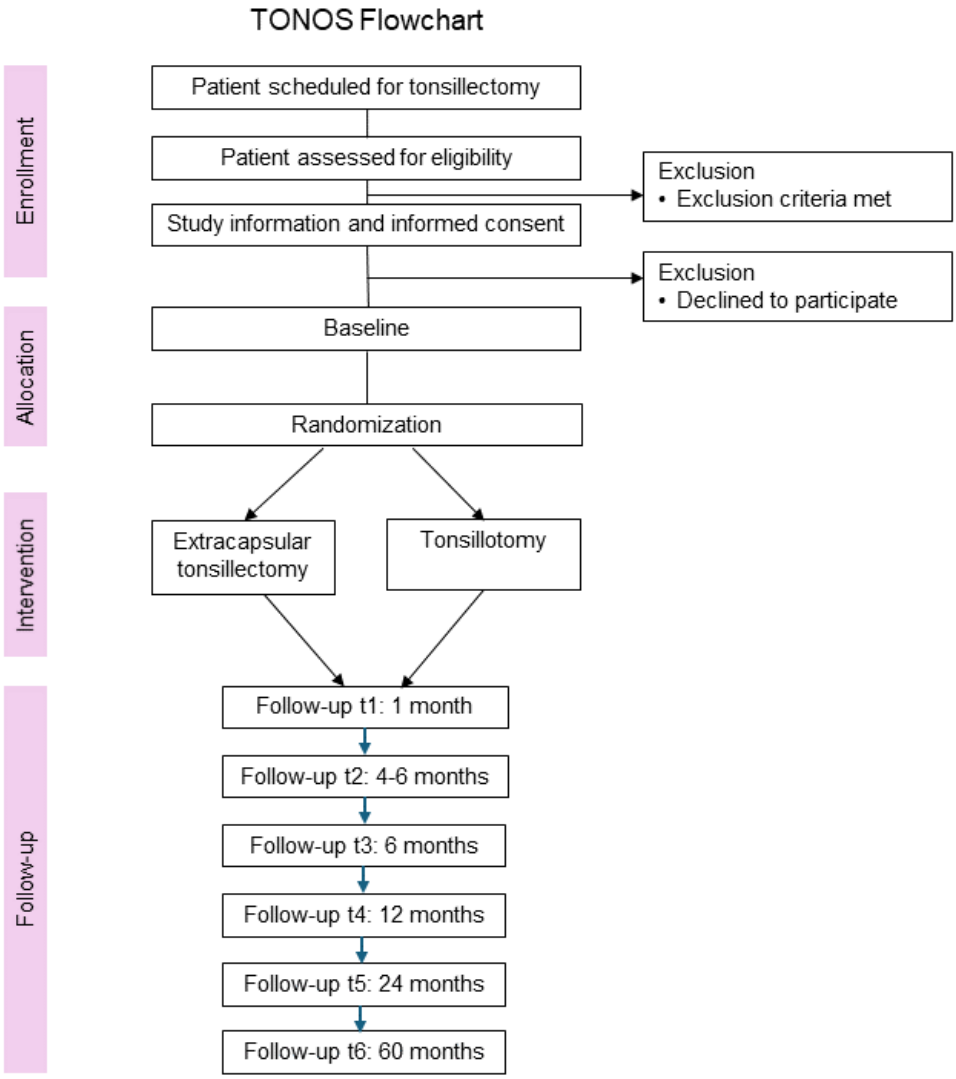
Data collection

Patient characteristics include occupation, smoking, age, height, weight, smoking history, tonsil size, tongue position, earlier treatment for OSA, comorbidities and OSA symptoms. Surgical data comprise instrumentation for dissection and hemostasis, and the surgeon's percentage estimate of tonsillar tissue removal.

Changes in AHI at baseline and after surgery, measured with home sleep study. AHI is calculated with the latest valid American Academy of Sleep Medicine criteria. Changes in nocturnal desaturation measured with oxygen saturation (SaO_2) mean, min, and SpO_2 <90% (T90) and ODI3, measured with home sleep study.

Changes in daytime sleepiness, measured with ESS; changes in insomnia symptoms, measured with ISI; changes in quality of life, measured with GHQ-12; changes in depressive symptoms, measured with DEPS; changes in OSA symptoms, measured with NTSR and structured questionnaire; reported by patients with an electronic data capture platform.

Figure 1: Flowchart (TONOS trial)



Data management

Data will be recorded in online database using REDCap platform (University of Turku) and on the servers of The wellbeing services county of Southwest Finland (VARHA). All data will be managed confidentially, and the information in the datasets is pseudonymised. Case report forms (CRF) are used to gather data from participating study sites, and then recorded in online database. Data are gathered from the outpatient clinical visit before and after the surgery, from the phone interviews and from questionnaires filled in by the study patients. The research coordinators will monitor the proper completion of questionnaires. The electronic system (REDCap) will sen automated reminders, and follow-up phone calls are made if necessary. The research coordinators will systematically validate data quality on a monthly basis, collaborating with the principal investigators and lead investigators of participating study sites when required. The principal investigators (JMP, HMS, JK) will be responsible of the common database with full access to the data. Online database will not be used for other purposes during the trial. Original data will be stored on servers managed by the University of Turku and VARHA, in Finland for 20 years. Original CRFs will be stored at the coordinating study center in a locked designated room. Access to the research data is restricted to the named members of the research team. The data will not be archived unless a justified public interest arises. The principal investigators are responsible for data deletion or archiving decisions.

Statistical considerations

These are stated in the Statistical Analysis Plan in the Appendix.

Ethics approval

The present protocol and applied informed consent forms were approved by the Medical Ethics Committee of the Wellbeing Services County of Southwest Finland. The trial will be conducted with the principles enunciated in the Declaration of Helsinki.

Consent

Each patient has a home sleep study and a clinical assessment before they are assessed for eligibility to enter the trial. The participating ENT specialist assesses eligibility, provides the potential participant with a verbal description of the trial and, if interested, provides a comprehensive Participant Information Sheet (PIS). All potential participants are given sufficient time to read the PIS, ask questions and consider participation before being asked to provide written informed consent if they are willing to participate. Prior to randomization and surgery, all patients participating in the study will give a written informed consent.

Confidentiality

These are stated in the Data Protection Form in the Appendix.

Post-trial care

Participants will receive ancillary care beyond the scope of the trial as required.

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