

# Postoperative Controls of ventilation tubes in children - by general practitioner or otolaryngologist? Study protocol for a prospective, multicenter, randomized study (The ConVenTu study)

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## Study protocol

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# Abstract

**Background:** Insertion of ventilation tubes (VTs) in the tympanic membrane is one of the most common ambulatory surgeries performed on children. Postoperative care may continue for two or more years and is today mostly done by otolaryngologists. Postoperative care given by general practitioners (GPs) may represent a sufficient level of health care regarding clinical outcome, but there exist no evidence-based guidelines concerning the level of expertise for this task. The aim of this study is to evaluate whether postoperative care after surgery with VTs performed by GPs represent a sufficient alternative to otolaryngologists.

**Methods/design:** Prospective study of postoperative care after surgery with VTs in children aged 3-10 years. At discharge, each patient is allocated randomly to postoperative care by either otolaryngologist or their regular GP. Study participants are enrolled consecutively from seven different hospitals in Norway until 200 patients are included in each study group. Hearing thresholds, middle ear function, complication rate, health related quality of life and the guardians' experiences two years after surgery, will be compared.

**Discussion:** Results from the ConVenTu study are expected to contribute with knowledge regarding optimal postoperative care after surgery with VTs.

## Background

Otitis media with effusion, defined as middle-ear effusion without acute signs of infection, is the major cause of acquired hearing problems in children (1). Some of the affected children need surgery to reduce ear complaints and to improve hearing, middle ear function and health-related quality of life (HRQoL) (2, 3). During surgery a small incision is made in the tympanic membrane to drain the fluid from the middle ear. Then a tiny ventilation tube (VT) (also called tympanostomy tube or grommet) is placed in the opening to keep the middle ear ventilated and prevent fluid from accumulating again. Indications for surgery is persisting otitis media with effusion or recurrent otitis media (3, 4). Surgery with VTs is one of the most common ambulatory surgeries performed on children (4). In Norway, about 6700 children undergo surgery annually (5).

Postoperative care may continue for two or more years to "assure that the tubes are functional, hearing loss has been corrected, and potential complications are properly diagnosed and managed" (6). A meta-analysis concluded, however, that sequelae after VTs are generally transient (otorrhea) or cosmetic (focal atrophy, tympanosclerosis) (7). Nevertheless, VTs that are not spontaneously rejected within two-three years are recommended to be removed surgically to avoid persistent perforations (8, 9).

Despite the large annual number of surgeries with VTs, there exist no evidence-based consensus regarding frequency and the level of expertise sufficient for the postoperative controls (9-11). A Dutch study found that most postoperative controls did not lead to any clinical interventions and therefore questioned the need for regular follow-ups (12). The Swedish Council on Health Technology Assessment completed a systematic literature review focusing on the documentation of VT treatment, but did not reach a conclusion regarding optimal postoperative care of healthy children with inserted VTs (10). The Norwegian Society of Otorhinolaryngology, Head- and Neck Surgery recommends that postoperative care is performed by otolaryngologists (8). Consequently, otolaryngologists are doing most of the postoperative controls in Norway, but occasionally this is done by GPs (13).

In a previous retrospective study we have reported no difference in hearing thresholds and middle-ear function two years after VT surgery between children receiving postoperative care by otolaryngologists and by their regular GPs (14). However, the low sample size and lack of randomization did not allow final conclusions on whether postoperative care

performed by GPs represent a safe alternative to otolaryngologists regarding clinical outcome. Moreover, we did not examine complication rate, HRQoL of the children or the guardians' evaluations of the postoperative care.

To confirm or reject previous findings with a higher level of scientific evidence, we decided to carry out a larger, prospective randomized study. The aim of our new study "Control of Ventilation Tubes" (ConVenTu) is to increase knowledge about which professional level in the healthcare system is sufficient for performing safe postoperative care of otherwise healthy children after surgery with VTs. The primary outcome measure is hearing thresholds measured two years after surgery, and we will compare children that receive postoperative care by otolaryngologists and by their GPs. We will also compare middle ear function, complication rate, HRQoL of the children and guardians' evaluations of the postoperative care. Results from our study may be utilized for deriving evidence-based clinical practice guidelines, and it is our intention to come up with recommendations for sufficient postoperative care after surgery with VT.

## Methods

### Study design and setting

The ConVenTu study is a prospective multicenter, randomized study conducted in clinical settings in seven hospitals located in all four Regional Health Authorities in Norway. The postoperative care is committed by either an otolaryngologist at the hospital where they had VT surgery, or by the patients' regular GP. A flowchart of design and timeline in the study is presented in figure 1, and a SPIRIT schedule of enrolment, interventions, and assessments in figure 2.

The Department of Otolaryngology, Head and Neck Surgery at St. Olavs Hospital is the main investigator site and coordinator of the study. The study is performed in collaboration with the Norwegian University of Science and Technology (NTNU). The project team leader and main project coordinator have regularly communication. Study visits have been performed at all study sites. In addition, meetings with all study sites are held annually or more frequently.

### Eligibility criteria

Eligible to participate are children, age 3-10 years, where VTs are placed in one or two ears. Exclusion criteria are conditions that are in need of closer postoperative care by otolaryngologists; for instance medical syndromes (e.g Downs syndrome), other coexisting severe diseases, or severe neurogenic hearing loss in at least one ear (we have excluded children with > 50 dB hearing thresholds in at least one frequency 0.25 - 4.0 KHz). Also, children with cognitive impairment or no comprehension of Norwegian language are excluded.

### Random allocation of postoperative care

At discharge from hospital, each patient that agreed to participate, is randomly allocated to receive postoperative care either by an otolaryngologist or by their regular GP (Figure 1). The randomization procedure is computerized and carried out by means of the 'WebCRF' (Clinical Registration Form) software developed at Unit for Applied Clinical Research at The Faculty of Medicine and Health Sciences, NTNU (15). The design is block randomization with varying size of blocks, with an allocation ratio of 1:1, stratified on study center.

### Procedures for postoperative controls

Children randomized to postoperative care by otolaryngologists will get an appointment at 6, 12 and 18 months after surgery, to reflect the existing management of these patients in Norway. Postoperative care by GPs will not be at fixed appointments, but on the initiative from the guardians as this reflects existing management in general practice. Guardians of children randomized to the GP group will receive written information on when to contact their GP; for

instance, if the child has otorrhea, persistent reduced hearing, or otitis media. The GPs receive information about the study and a procedure for postoperative care and how to treat the most common complications. In addition, a procedure for handling of complications is enclosed in the discharge report after surgery, so it is available for the GP at point-of-care. If needed, as judged by the GP, the children will be referred to an otolaryngologist. If the VTs have not been spontaneously rejected within 18 months, the GP is requested to refer the patient to an otolaryngologist. Accordingly, the guardians are told to contact the GP latest 18 months after surgery (Figure 1).

### **Assessment of clinical and sociodemographic factors**

All participants will be evaluated with audiological tests and questionnaires before surgery and two years after. Audiological tests are performed with audiometry and tympanometry. Hearing thresholds are measured by pure tone audiometry. In the youngest children equipment for play audiometry is used if needed (16). Results from at least three of the pure tone thresholds in dB at 0.5-1-2-4 kHz form the pure tone average (PTA). Two years after surgery all participants will be examined by an otolaryngologist. Complications during the postoperative period will be registered by carefully examining the patient record.

Sociodemographic information is assessed at enrollment. At the end of the follow-up period the guardians evaluate the postoperative care. Both before and two years after surgery the guardians are asked to complete questionnaires regarding their perception of the child's HRQoL (see secondary outcome).

Each study center has a local coordinator responsible for a Case Report Form to ensure complete recording of individual data.

### **Outcomes**

PTA in dB is defined as primary outcome variable.

The following clinical and sociodemographic factors are considered as secondary outcomes:

1. Middle ear function assessed with tympanometry and otomicroscopy (17)
2. Complication rates
3. Disease specific HRQoL by the otitis media questionnaire for children ('OM8-30') (18)
4. Generic HRQoL by 'PedsQL', based on proxy-report (participants aged 3-8 years) or by adolescent self-report (8-12 years) and 'SDQ-Nor' (19, 20)
5. Guardians evaluation of the postoperative care

The secondary outcome measures no. 1-2 act as surrogate markers for possible reduced hearing in the future. Complications after insertion of VTs include otorrhea, occlusion of tubes, premature extrusion, persistent perforation in the tympanic membrane, retraction pocket and cholesteatoma (6, 7, 21). The secondary outcome measures no. 3-5 is assessing the risks and benefits of postoperative care and important for patient-centered care.

### **Participant timeline**

See Figure 1 and Figure 2

### **Sample size and power**

We defined equality in the main outcome variable (PTA two years after surgery) as < 5dB, and 5dB as the minimal clinically important difference (equivalence margin), since measurements of hearing thresholds are determined in 5dB

steps (22). To avoid an incorrect conclusion about no difference between the groups (Type II error), the power of the tests for detecting a difference of  $\geq 5$  dB must be high ( $\geq 95\%$ , error margin  $<5\%$ ). Thus, with a power of 95% and a significance level of 5% (two-sided test), 105 participants is needed in each group to be able to detect an absolute difference in PTA between the groups of  $\geq 5$  dB (standard deviation of 10 dB in each group). With additional 15% for dealing with potential skewed distributed variables, and further a 20% increase to account for potential dropouts during the follow-up period, we are left with a sample size of 145 participants in each group. To maintain power in an analysis stratified for seven study centers (six additional parameters in model), the total sample size must be increased by at least 60 participants, applying general rules of thumb of at least 10 cases per parameter. This leaves us with a sample size of at least 175 participants in each group if we assume that the 60 participants are evenly distributed in the two randomization groups. We chose to truncate upwards to 200 participants in each group (Figure 1) to maintain power in case of a higher dropout rate or a need for additional adjustment factors in the model.

## Statistical analysis

The analyses will be performed according to intention-to-treat. A general linear model and/or a linear mixed model (LMM) will be applied to compare PTA and mean change in PTA after two years. Similar methods will be applied for other relevant variables that are measured on a continuous scale (HRQoL). Log-transformation, or non-parametric methods, may need to be considered. Generalized linear mixed model, and/or McNemar's test is relevant for analyzing changes in categorical, dichotomous outcome variables. A Chi-square test is relevant for comparing the two study groups with respect to number of complications during postoperative care. Equality between the two treatment groups will be evaluated in terms of the magnitude of observed differences (point and interval estimate).

## Discussion

Insertion of VTs is among the most common surgical procedures in childhood and postoperative care can take years (4). Evidence concerning which level in the health care system sufficient to handle the postoperative controls is lacking (8-10, 12, 23). Possible disadvantages of postoperative care carried out by GPs could be lack of knowledge and equipment, and failure to handle possible complications. On the other hand, possible benefits could be shorter travelling distance, increased flexibility of time point of controls, and better continuity of care for the patients and guardians (24). It is therefore important to evaluate whether postoperative care performed by GPs represent a sufficient alternative to otolaryngologists concerning clinical outcome.

One of the major strengths of this study is that it is designed to detect a small difference in hearing thresholds ( $\geq 5$ dB). There is no evidence or consensus regarding the minimal clinically important difference for improvement in hearing level as far as we know. Several methods have been proposed, Chow et al defined 10dB as being of clinical importance (25). Because our study affects children, we wanted to be sure that we did not incorrectly conclude with no differences in main outcome. Therefore, we wanted to be more conservative. In clinical practice, threshold measurements are determined in 5 dB steps, and consequently this is the lowest change in dB possible to detect in our study. Another strength is that the study also includes evaluation of middle ear function and complication rates two years after surgery, HRQoL of the children, as well as the guardians' evaluation of the postoperative care. Moreover, participants are recruited from all different regions of Norway.

A limitation of our study is that it covers only ages 3-10 years, although also younger children receive VTs (26). The reason for not including younger children are the difficulties of getting reliable audiological tests prior to surgery (27). Another limitation is that the study is not designed to uncover long-term complications after VTs which occurs later than two years after surgery. However, this is done in other studies, although not by means of different postoperative care (28).

The ethical concerns in this study are related to whether children that are randomized to postoperative care by GPs may be at risk of poorer clinical outcome. Therefore, all participants are thoroughly examined two years after surgery. There is no summoning to postoperative controls in general practice, so there is a risk that guardians do not book an appointment when needed despite the information given. However, in our previous retrospective study with similar design, a lack of attendance in the GP group was not a problem (14). Moreover, children with an expected increased risk of complications, with severe neurogenic hearing loss or other severe coexisting diseases are excluded from the study (See "Eligibility Criteria"). If the GP finds that the child needs to see an otolaryngologist, he or she will refer the child. The Ethical Committee that reviewed the study did not have any comments on this procedure.

We believe that the findings of this study will be of interest internationally. However, the transferability to other countries presupposes a well-developed primary health care. The setting for this study is Norwegian healthcare. Norway has a GP scheme, and nearly every citizen has one specific GP to consult, therefore the guardians will know which GP to contact (29). General practice is organized in a way that patients seek help when they need it and is easily available (30). Patients are normally not summoned to controls. This contrasts with the hospitals where summoning patients to outpatient controls are normal. Patients can normally not seek a public specialist or hospital without a referral from a GP (31). As different countries are organizing their primary health care differently, cautions must be taken when interpreting the results.

### **Trial status**

This trial started inclusion of study participants in August 2017 and the recruitment period is estimated to be three years. A challenge in the study has so far been slow recruitment of participants; we are considering prolonging the data recruitment period to reach our target of 400 participants. The follow up period is two years, and the data collection phase are expected to be completed in fall 2022. All personnel who have contributed significantly with the planning and performance of the study may be included in the list of authors in accordance to the Vancouver rules (32). The results of this study will be submitted for publications in peer reviewed journals and communicated to the participants and the Ethics Committee according to EU and national regulations. It is our intention with this study to come up with new knowledge regarding optimal postoperative care after surgery with VTs.

## **Declarations**

### **Acknowledgements**

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### **Authors' contributions**

BA, AHN, ASH, and WMT conceived and designed the study. GA performed the sample size calculation. BA wrote the first draft of the manuscript. BA, AHN, ASH, GA, SN, and WMT

contributed to the writing and review of the manuscript and approved the

final version. All named authors adhered to the authorship guidelines for *Trials* and have agreed to publication. No professional writers were involved in this manuscript.

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Regional Health Authority (Samarbeidsorganet).

The funding body has no role or ultimate authority in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

### **Availability of data and material**

The datasets generated during and/or analysed during the current study are not publicly available due Norwegian regulations concerning sensitive data but are available from the corresponding author on reasonable request.

### **Ethics approval and consent to participate**

This study was reviewed and approved by the Regional Committee for Medical and Health Research Ethics (REC) in Mid-Norway (2015/902). The study will be conducted according to the Declaration of Helsinki and ICH-Good Clinical Practice guidelines and follow the CONSORT rules (33, 34). Protocol modifications will be reviewed by REC and Clinical Trials. Processing of personal study data will be done according to procedures approved by the data protection official at each study center.

Guardians must give written informed consent on behalf of themselves and their children in order to participate. In addition, children 8 years and older will be informed of the study.

### **Consent for publication**

Not applicable

### **Competing interest**

The authors declare that they have no competing interests.

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# Abbreviations

VT: Ventilation tube

GP: General Practitioner

HRQoL: Health-related quality of life

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# Figures

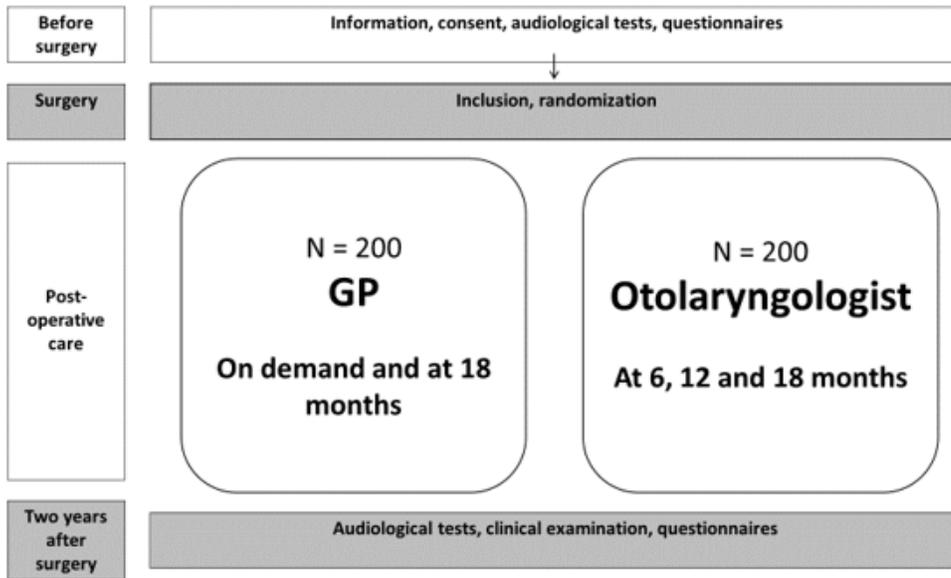


Figure 1

## Flowchart

TIMEPOINT	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
	Before surgery	Surgery	6 months	12 months	18 months	24 months
<b>ENROLMENT:</b>						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
<b>INTERVENTIONS:</b>						
Postoperative care by GP			←————→			X
Postoperative care by otolaryngologist			X	X	X	
<b>ASSESSMENTS:</b>						
<b>Baseline variables:</b>						
→ PTA in dB						
→ Tympanometry						
→ <del>Spoken communication</del> information	X					
→ HRQoL: 'OM 8-30', 'PedsQL', 'SDQ-Nor'						
<b>Outcome variables</b>						
→ PTA in dB						
→ Middle ear function (tympanometry and <del>otoscopy</del> )						X
→ <del>Communication</del> rates,						
<b>List other data variables</b>						
→ HRQoL: 'OM 8-30', 'PedsQL', 'SDQ-Nor'						X
→ Guardians evaluation of the postoperative care						

Figure 2

Schedule of enrolment, interventions, and assessments. \*PTA=Pure Tone Average, dB=decibel, HRQoL=Health Related Quality of Life, OM8-30, PedsQL, SDQ-Nor: see manuscript

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [ConVenTu2020.01.20SPIRITChecklist.docx](#)
- [DemografiogaudiologiBaseline.doc](#)
- [PedsQL57aar.ForeldrerapportPRE.doc](#)
- [Twoyearsaftersurgery.pdf](#)
- [NorskOM830.pdf](#)
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