



Information letter from the Tonsil Surgery Register

Background

The Tonsil Surgery Register registers patients who are treated surgically for a tonsil infection or for enlarged tonsils. Surgical treatment of tonsils is one of the most frequent surgical procedures performed on children and young people in Norway. Approximately 8,000 tonsillectomies are performed every year at public hospitals or by private surgeons who are reimbursed from the public purse.

Purpose

The purpose of the register is to ensure appropriate and safe treatment for the whole patient group, and to improve our knowledge of the treatment in relation to both individual patients and the patient group as a whole. The Register can help to ensure that better, more uniform treatment is offered, and increase interest and research in the field, as well as ensuring that the general population is better informed.

What information will be registered?

The following information is registered: name, date of birth and national ID suffix, indication for surgery, treatment, possible complications after the procedure and patient-reported benefit.

See the website <https://stolav.no/norsk-tonsilleregister> for a detailed description of the register.

Where will the information be taken from?

In order to assess the quality of the treatment, we need to collect information about you before, during and after treatment. This information is registered by the surgeon after the operation, and a questionnaire will be sent to you electronically 30 days and 6 months after your operation.

Right of access, right to rectify information, and right to opt out

Pursuant to the Sections 24-25 ff. of the Personal Health Data Filing System Act, you may at any time request access to the information registered about you, or demand that the information be rectified or erased. You have the right to opt out of your personal and health data being stored and used in the Tonsil Surgery Register. If you do not wish information about you to be stored, you may, at any time and without stating a reason, opt out of registration. It will have no bearing on your treatment if you choose to opt out, or if you wish to withdraw at a later date. The information about you will then be erased from the register. However, as the data controller, St. Olavs Hospital will continue to process the information insofar as this is necessary for it to fulfil its duty to ensure that persons who have opted out of registration are not subsequently re-registered. Erasure of data does not involve erasing anonymised research files that have already been used in research.

You can opt out of registration by logging on to www.helsenorge.no, by giving notification of this in connection with your operation or by contacting the Tonsil Surgery Register. You will find a guide to the right of access to information, erasure and the restriction of information at <https://tjenester.helsenorge.no/helseregistre> and on the website <https://stolav.no/norsk-tonsilleregister>.

You can contact the Norwegian Data Protection Authority or the Norwegian Board of Health Supervision if you believe that your health data are not being processed in accordance with the Regulations relating to medical quality registries or other relevant regulations.

Laws and regulations

The Tonsil Surgery Register is regulated by the Regulations concerning medical quality registries, the Personal Health Data Filing System Act and the General Data Protection Regulation. The Register will be used to carry out tasks that are in the public interest, and its legal basis is the General Data Protection Regulation Article 6 (1) letter e) and Article 9 (2) letters g), h), i) and j). The Personal Health Data Filing System Act and the Regulations concerning medical quality registries supplement this legal basis in



Norsk Kvalitetsregister Øre-Nese-Hals, Tonsilleregisteret

domestic law. Information about your contact with the specialist health service can be obtained and used by the register without your consent, but you have a right of access to the information and you have a right to opt out of the register processing your data. The data in the Register will be stored for as long as the Register has a lawful basis for doing so pursuant to the General Data Protection Regulation Article 6 (1) letter e) and the Regulations concerning medical quality registries, and for as long as it is relevant and necessary for the purposes for which they are processed.

Data are registered electronically and are protected against unauthorised access. All information will be processed with respect for data protection and privacy and in compliance with applicable laws and regulations.

Processing of data in the register

The data in the Register are stored in de-identified form, meaning that the date of birth and national ID suffix are replaced by a code. All persons who have access to the data in the Register are subject to a duty of confidentiality. Your personal data may only be disclosed, or otherwise made available, in accordance with laws and regulations, including rules relating to the duty of confidentiality and the European General Data Protection Regulation (GDPR). Information from the Register can be used in the management of the health service, to improve the quality of treatment and for research purposes.

It will be possible to retrieve information from patient records to clarify details about the diagnosis and the treatment given. It will also be possible for the Register to retrieve and collate relevant additional information from other national medical quality registers and health registers established pursuant to the Personal Health Data Filing System Act Sections 8 to 11, using information in the National Population Register and socioeconomic data from other public registers. Examples of relevant public registers and population surveys: the Norwegian Patient Register, the Medical Birth Register of Norway, the Norwegian Prescription Database, the Cancer Registry of Norway, the Cause of Death Register of Norway, Statistics Norway's registers, the FD-Trygd Database, the Norwegian Labour and Welfare Administration (NAV), the Directorate of Taxes' databases, population surveys that are part of Conor, relevant ENT sub-registers, the national health surveys programme, the Tromsø Study, HUNT and KUHR (control and payment of reimbursements to health service providers). Data will regularly be linked to the Norwegian Patient Register in order to measure the coverage and validity of the Tonsil Surgery Register.

Collaboration has been established with other Nordic tonsil surgery registers. The plan is to regularly compare anonymised data sets, and to initiate international research based on the different registers. You may also be invited to participate in special research studies that are related to the purpose of the register.

All collating of data requires prior approval from publicly approved bodies. It will not be possible to identify individuals from results based on analyses from the register.

Annual national reports will be prepared by the register, and data will be made available to the general public on the websites mentioned below. Results will also be published on a continuous basis at professional conferences and in national and international medical journals.

More information about the register: www.kvalitetsregistre.no and <https://stolav.no/norsk-tonsilleregister>

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