



Consent - Request for Registration in the National Tonsil Surgery Register:

Background and purpose

This is a request asking you to register in the National Tonsil Surgery Register. Surgical treatment of throat tonsils is one most common procedures on children and youths in Norway with approx. 10,000 operations each year. Tonsils can be fully removed (=tonsillectomy) or partly removed (=tonsillotomy). Tonsillectomies are the most common.

Tonsils are generally removed for two reasons:

1. Chronic/recurrent tonsillitis.
2. When enlarged tonsils make swallowing and breathing difficult, with reduced sleep, fatigue and concentration problems during the day.

In order for the offered treatment to be as good as possible, more knowledge about the entire patient group is needed and registration will help. Registration in the National Tonsil Surgery Register is voluntary and requires informed consent. This means that you must sign a declaration of consent in order for us to register you in the register.

The register will contain the following information about you:

The information recorded in the register will include your name, personal identification number, and information about given diagnoses and treatment. Other information, such as the surgical equipment used during the procedure, any later complications and whether your complaints subsided will also be recorded in the register. Blood tests and any other tests are *not* routinely taken in connection with the treatment. The Central Norway Regional Health Authority is responsible for handling data included in the register. Information is recorded electronically and is secured against inspection by intruders.

The Norwegian Data Protection Authority has given concessions to the register and information will be stored in accordance with applicable provisions governing concessions. All gathered information is handled confidentially. Everyone who works with information from the register is subject to confidentiality about all matters that come to their knowledge.

The gathered information will be available to the department/hospital that treated you.

From where will the information be gathered?

To assess the quality of the treatment, we need to obtain information about you prior to, during and after treatment. The information is gathered through surveys and conversations before the operation, by telephone, letter or electronically after 30 days and six months, respectively. ***You will receive a message in Digipost, from helsenorge.no or in an e-mail, and a text message from the National Patient Reported Outcome Measures. It is important to answer all the questions.***

Right to inspect, change and delete information

You can inspect any of the recorded information about you at any given time. In addition, you have the right to correct any errors in the information we have recorded in the register. You can also demand to have your recorded information deleted from the register without giving a reason. The deletion of data will not include deletion from anonymised research files that have already been used in research. Your treatment programme will not be affected if you refuse to register or choose to withdraw later.

Information from the register will only be supplied in the form of unidentifiable lists. That is, all information will be handled without names and personal identification numbers or other directly recognisable information. A code links you to your information through a list of names. Only authorised personnel are linked to the register. They can access the list of names and connect it to you. For research purposes, it might be necessary to compare information from the register with other information from the hospital's medical records and the following registers: The Norwegian Patient Registry, The Medical Birth Registry of Norway, The Norwegian Population Registry, The Norwegian Prescription Registry, The



Norwegian QA Register Ear Nose and Throat - Tonsil Surgery Register

Cancer Registry, The Norwegian Cause of Death Registry, Statistics Norway, The Norwegian Labour and Welfare Administration (NAV) and population surveys included in Conor (Cohort of Norway), National Health Surveys and the Health Survey in Northern Norway. Connection to the Norwegian Patient Registry and the Prescription Registry will be done regularly to measure the level of coverage and validity of the Tonsil Surgery Register.

Cooperation has been established with Nordic Tonsil Surgery Registers. Comparison with anonymised datasets is planned once per year, in addition to the implementation of international research based on the various registers.

Annual national reports from the register will be prepared and the data will be available to the public on the web site. Results will be continually published at expert meetings, and in national and international medical journals. It will not be possible to connect results based on analyses from the register with particular individuals.

Further information about the register and how information obtained from the register will be handled is available on www.kvalitetsregistre.no

All research projects must be approved in advance by the Norwegian Regional Committee for Medical and Health Research Ethics (REC) and other public offices, as required by law. Information about a project will be available on the web site once it has been approved.

For more information about tonsil surgery, we recommend the following web site www.halsmandeloperasjoner.no

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