Version 1.3

INFORMATION ABOUT THE RIGHT TO OPT OUT AND PARTICIPATION IN NORWEGIAN VASCULITIS REGISTER (NorVas)

Background and purpose

Vasculitis is a common term for several rare and sometimes very serious diseases in which autoimmune inflammation of blood vessels occurs in the body. The pathological picture and symptoms vary according to which blood vessels and which bodily organs are affected. NorVas is a national medical quality register aiming to increase knowledge about systemic vasculitis diseases, ensure and improve the quality of diagnosis and treatment of vasculitis patients, map the need for support for the patient group and form a basis for prioritization of healthcare services, and contribute to research.

NorVas has had the status of a national quality register since 2016. The register forms the basis for treatments in article 6 no. 1(e) and article 9 no. 2 (j), and the regulations on medical quality records. In 2024, NorVas went from being a register based on consent to being reservation-based. This means that all patients from the age of 16, who are followed-up by a rheumatology department in Norway, are now automatically included in the register if they are diagnosed with ANCA-associated vasculitis or large vessel vasculitis – unless they have reserved themselves against such participation. See separate section on how to do this. Patients with known vasculitis, who have not previously been included in the register, are included at the first control at the rheumatology department after the register became reservation-based. Patients who have previously consented to inclusion in the registry will continue to be included, and no changes have been made to the information collected. Patients who previously refused to participate in the register must now actively opt out if they still do not wish to participate.

Universitetssykehuset Nord-Norge (UNN) is the data controller for the register, and will ensure that privacy rights are safeguarded. The general management of the register has been added to the rheumatology unit at the neuro-, skin- and rheumatology department (NEHR).

What to register and where to get the information from

The information will be collected from you as a patient and from your hospital records. The register collects demographic data (name, address, date of birth, social security number, education and job situation) and clinical information (diagnosis and time of diagnosis, medical history, disease activity, blood tests, injury development, medical treatment and any side effects). The information is collected in connection with regular consultations with a rheumatologist. You will be asked to answer questionnaires about your health status and your experience with disease activity, function and quality of life during the consultations (patient-reported data). The information is registered electronically and is protected from access by unauthorized persons. Everyone who works with the register has a duty of confidentiality.

What is a biobank

NorVas has the license for biobank, i.e. the possibility of collecting blood, urine and tissue samples from patients who are registered. In this case, the sample material will be stored and used in studies subject to approval from the regional committee for medical and health research ethics (REK). This may form a unique basis for studies of, for example, possible hereditary factors, disease-associated proteins or environmental exposures that affect the disease process. Analyses related to the course of disease and effect of treatment with medicines will also be possible. The managing director of NorVas is responsible for the biobank.

Research and quality improvement

In order to access registered data, researchers must submit an application that meets formal and scientific criteria. The application is assessed by NorVas' academic council. Upon approval, disclosure of data from the register will only include information necessary for analysis and evaluation of results. The data disclosed to the responsible for the study will not be directly personally identifiable. Results from research projects will be presented in a way that individuals cannot be recognized. All medical and health research must be approved in advance by the regional committee for medical and health research ethics (REK).

In order to assess the data quality and completeness of the register, the data in the register will be linked to the Norwegian patient register. For some research and quality improvement projects, it may be relevant to link information from NorVas with other public registers, as long as it is permitted by law and regulations and not in conflict with any reservations. Examples of such registers include the cancer register of Norway, the Norwegian kidney biopsy register and RevNatus (quality register for pregnancy and rheumatic diseases). It may also be relevant to compile anonymized data with foreign registers. All information will be treated with respect for privacy, in accordance with laws and regulations.

Reservation, storage, right of access, alteration and deletion of data

The data about you is stored for as long as it is necessary to achieve the purpose of the register in accordance with article 5 of the General data protection Act and section 6 of the Health register Act. All information in the register is strictly confidential. You do not have to take any action unless you wish to opt out of NorVas collecting information about you. If you choose to opt out, the data collected about you will be deleted. This will have no consequences for you in relation to further follow-up and treatment.

You have the right to know what is in the register and who has had access to the information or had it disclosed to oneself. You can request that information about you be deleted or corrected in accordance with the Personal data Act. An access report on registered information can be ordered by logging in to www.helsenorge.no. Data already published in scientific articles cannot be required deleted. If you believe that your health information is not processed in accordance with applicable regulations, you can contact the Norwegian data protection authority or the Norwegian board of health.

How to opt out?

You can opt out by yourself by logging in to www.helsenorge.no. The procedure is available on the register's website www.norvas.no. You can also contact your local rheumatology department or register directly by phone or email. In the case of the latter, for privacy reasons, we will contact you by telephone afterwards to obtain your social security number for secure identification. All information about you in the register will then be deleted.

UNN HF has a data protection officer who can give general advice on your rights with regard to personal data protection: personvernombudet@unn.no, telephone 777 55855.

Contact information

Norwegian vasculitis register, UNN HF, Postboks 20, 9038 Tromsø
Website: www.norvas.unn.no
Email: norvas@unn.no
Registry secretary: Mai Lisbet Berglund at the registry unit, telephone 776 69015
Academic leader: rheumatologist Christine Karlsen and Julianne Elvenes