We would like you to participate in the Rare Anaemias Disorders European Epidemiological Platform (RADeep) and the Norwegian Anaemia Registry.

Purpose of the registry and why you are being asked

Your child is being monitored for congenital (hereditary) anaemia. This disease requires medical follow-up.

We would like your child to participate in the Norwegian Anaemia Registry and the European Anaemia Registry (RADeep). Both are quality and research registries. The Norwegian Anaemia Registry is owned by Oslo University Hospital, and the European registry is owned by EuroBloodNet, which is subject to EU.

Rare anaemias are a group of diseases characterised by the body not producing enough haemoglobin, which affects fewer than 5 out of 10 000 people. Some people need regular blood transfusions, while others will only need blood transfusions occasionally. In some conditions with anaemia, completely different treatment approaches may be appropriate. Patients with such anaemias need to be monitored throughout life due to the challenges and complications of the disease and its treatment. We collect data from as many patients as possible, in order to conduct research on various diseases, improve healthcare services and develop treatment methods. Rare diseases have few patients in each country, so cooperation across national borders is necessary to be able to collect enough information.

RADEEP: The purpose of RADeep is to collect health data across European countries to promote research and develop new treatment options, increase knowledge and promote equal treatment throughout the European Union. The information in RADEEP is anonymised, so nobody will know anything about you and your illness.

Norwegian Anaemia Registry: The Anaemia Registry is owned by Oslo University Hospital. Both the information in the research registry and the clinical information about you are updated annually so that we can monitor your treatment. Only authorised personnel at the clinic have access to this database and the information stored here does not identify any of the participants. It will not be possible to recognise or identify you in any of the reports or scientific publications that are created.

How is RADeep organized

RADeep: The European Union (EU) has founded 24 comprehensive collaborative networks for rare diagnoses, called the European Reference Network (ERN). The purpose of the networks is to ensure equal access to treatment for rare diseases in all European countries.

EuroBloodNet, www.eurobloodnet.eu, is one of these 24 networks and focuses on rare blood diseases. One of the sub-registries of EuroBloodNet is RADeep (Rare Anaemia Disorders European Epidemiological Platform, www.radeepnetwork.eu). This is a digital platform that transfers selected data to EuroBloodNet.

TOLKENETT
Tolkenett AS
Schweigaardsgate 12
0185 Oslo
Org. nr. 993 965 294
www.tolkenett.no

RADeep is operated and owned by the EuroBloodNet Association, which is led and controlled by a collaboration between three hospitals in Spain, Belgium and Cyprus. These three hospitals have the primary responsibility for ensuring that collected information is stored in accordance with Article 26 of the GDPR (EU Data Protection Directive). Each individual partner, such as Oslo University Hospital, is also subject to and controlled by their own data protection officer.

RADeep is financed by public and private funds; you can read more about this on the following website: www.radeepnetwork.eu/about/radeep-funding

Norwegian Anaemia Registry: Information about the Norwegian Anaemia Registry can be found here: www.oslo-universitetssykehus.no/fagfolk/forskning/Sider/Forskning.aspx. You are welcome to contact us if there is anything you would like to ask about.

What does this mean for you?

Consenting to research project participation

For RADeep, we collect and register anonymous information about your child. The information in the OUS anaemia registry will not be de-identified. The information recorded in both registries includes various health information such as blood test results, information from your family doctor, other specialists, hospital admissions, medications and medical complications. There may also be a need to retrieve information from central health registries such as the Cancer Registry, Medical Birth Registry, Cause of Death Registry, National Patient Registry, Prescription Registry and more. The managing director of OUS has overall responsibility for all processing of such data.

One of the purposes of RADeep and OUS anaemia registry is research projects. All requests for research will go through your doctor. You can always withdraw consent or refuse to participate in research projects without any disadvantage to your child.

Possible advantages and disadvantages

Participation in the registry will provide increased knowledge about congenital anaemias, which we hope can lead to better follow-up and treatment. This may be useful to your child in the future.

Participation in the registries will not require any additional time for you and your child will not have to take any additional tests. You will not receive any financial benefit from participating. RADeep and the Norwegian Anaemia Registry have good privacy security systems. Anyone who has access to the information in RADeep is prohibited from identifying the personal information. If you have shared sensitive information about your child publicly, there is still a small risk that the data coming from your child can be recognised, and we recommend that you be careful about sharing sensitive information about your child on public websites. We will always contact you if any findings are made in tests that have or may have an impact on your child's illness/health.

Voluntary participation and the right to withdraw your consent

Participation in the registry is voluntary. If you wish to allow your child to participate, please sign the

Consent Form on the last page. You may withdraw your consent at any time and without giving any reason. There will be no negative consequences for your child or his/her treatment if you do not want to participate or later choose to withdraw. If you withdraw consent, no further research will be conducted on the stored information. You can demand access to the data stored about your child. This will then be disclosed to you within 30 days.

The right to demand destruction, deletion or disclosure does not apply if the data has already been used for published research. contact details on the last page).

If you later wish to withdraw or have any questions, please contact the project manager (see the contact details on the last page).

What happens to the informasjon we have about you?

RADeep: The data we record about your child should only be used as described in the objectives for the RADeep and OUS anaemia registries. The information will be stored in RADeep as long as needed, and an assessment will be made every 15 years whether the data is still needed. The information is stored according to the EU's data privacy regulations, cf. GDPR 2016/679, and in accordance with the EU's guidelines for rare disease registries.

All information will be processed without name and personal identity number or directly recognisable information (=coded data). A code links your child to the information through a list of names. Only paediatricians and haematologists who work with the registry have access to this list.

Norwegian Anaemia Registry: The information in the Norwegian Anaemia Registry is stored for as long as needed, and for a duration of 30 years after the age of 18 (if the consent was signed before the age of 18). After this, the consent must be signed again, if necessary to maintain the registry. The basis for processing data for the registry is the EU Data Protection Directive (GDPR), Article 6 #1a and Article 9 #2a.

You and your child have the right to access the information that is registered about your child and the right to have any errors in the information that is registered corrected. You and your child also have the right to access the security measures when processing the information. You and your child can appeal to the Norwegian Data Protection Authority and the data protection officer at OUS about how we process the data.

Sharing the data and transfer to countries inside and outside the EU

For both registries, clinical information can be used by other collaborative research groups in Norway or abroad. This may include countries with poorer privacy protection than in Norway, but then the information will always be de-identified. You can contact the clinic if you would like more details about how your information is used.

All studies must be formalised in accordance with data protection legislation.

RADeep: RADeep is responsible for ensuring that the transfer of information is in accordance with EU data protection legislation (GDPR). This also applies to countries outside the EU. Nobody is allowed to attempt to identify your child. The code that links your child to personally identifiable information will not be disclosed.

In order to obtain data for a planned project, a written application must be submitted to the Data Access Committee in RADeep, which consists of healthcare professionals, lawyers, ethical experts and user representatives, who assess whether the project is in accordance with guidelines and purposes.

You have access to all information about the use of the data and you can find more information about the legal framework and rules for the disclosure of data on RADeep on the following website: www.radeepnetwork.eu/about/radeep-legal-frame

Approvals

The Data Protection Officer at Oslo University Hospital has approved our use of RADeep and the Norwegian Anaemia Registry.

Contact

If you have any questions about the project or wish to withdraw from participation, you can contact haematologist Marte Holmboe Berg or paediatrician Tina Treu Os at the Center for Rare Diagnoses by phone: 23075340 or by email: titros@ous-hf.no.

If you have questions about privacy in the project, you can contact the data protection officer at Oslo University Hospital: personvern@ous-hf.no or by phone: 23 01 50 22