

Participant information sheet

Invitation to participate in the study

We invite you to consider taking part in a scientific research study. Before making a decision, please read this information carefully. It explains what the study involves, what will be required of you, the possible benefits and inconveniences, and your rights as a participant.

Participation in the study is entirely voluntary. You may discuss this information with your family, your treating physician, or another person you trust. Please ask any questions you may have. The research team will answer them before you sign the informed consent form.

Study title

“Effects of a 12-Week Moderate-Intensity Physical Activity Programme on Plasma Soluble Receptor for Advanced Glycation End Products (sRAGE) in Patients Receiving Maintenance Haemodialysis”

Study site: B. Braun Avitum Dialysis Centre, ul. Sienkiewicza 3, 64-300 Nowy Tomyśl, Poland

Principal Investigator: Leszek Niepolski, MD, PhD

Responsible institution / Sponsor: Poznań University of Medical Sciences

Ethics Committee approval number: 945/14

Why is this study being conducted?

People receiving maintenance haemodialysis have an increased risk of heart and blood-vessel disease. One of the markers being studied in relation to inflammation and vascular damage is a protein present in the blood called the soluble receptor for advanced glycation end products, or **sRAGE** for short.

The purpose of this study is to determine whether a 12-week moderate-intensity physical activity programme, tailored to each participant's capabilities, is associated with changes in blood sRAGE concentrations in people receiving haemodialysis. This is a scientific study. It is not intended to replace or alter your routine dialysis treatment.

Participation in the study may not provide you with any direct health benefit.

Why have you been invited?

You may be invited to participate if you:

- are at least 18 years of age;
- have been receiving haemodialysis treatment for at least 4 months;
- undertake physical activity at least once per week; and
- are willing to make lifestyle changes.

People for whom physical activity could involve increased risk will not be eligible for the study. This includes, in particular, people who are pregnant; have cancer, severe heart failure, severe chronic obstructive pulmonary disease, an acute illness within the previous 3 months, advanced degenerative disease affecting multiple joints, or substantial physical disability.

Final eligibility will be assessed by the research team, taking your health condition into account.

What does participation involve?

Your planned participation will last approximately **12 weeks**, preceded by a baseline assessment. Clinical assessments will be performed at the beginning of the study and again after approximately 12 weeks.

The study includes two groups. After you have signed the informed consent form and completed the baseline assessment, you will be randomly assigned to one of the groups. The probability of being assigned to either group is approximately 50%.

Intervention group

In addition to usual haemodialysis care, you will receive:

- education on an active lifestyle;
- an individually tailored 12-week moderate-intensity physical activity programme;
- advice to undertake physical activity at least three times per week, with a target weekly energy expenditure of at least 370 MET-minutes per week;
- a pedometer to record your number of steps and a physical activity diary;
- regular meetings and/or telephone contacts to discuss and monitor implementation of the programme.

Recommended activities may include walking, resistance-band exercises, medicine-ball exercises, stationary or outdoor cycling, or elliptical training. The type and intensity of activity will be adapted to your abilities, limitations, and clinical condition, and approved by a nephrologist.

Control group

You will receive standard haemodialysis care. You will not take part in the structured physical activity programme provided to participants in the intervention group.

What tests and measurements will be performed?

Your participation may include:

- completing a questionnaire concerning your current physical activity, exercise habits, and willingness to make lifestyle changes;
- measurement of body weight, height, and selected body circumferences;
- measurement of blood pressure before a midweek haemodialysis session, after at least 5 minutes of rest in a seated position;
- use of information related to your haemodialysis treatment, such as the duration of dialysis therapy, dialysis adequacy, and residual urine output;
- blood sampling before a midweek haemodialysis session while fasting, to measure sRAGE and selected routine or research laboratory parameters, including, among others, blood count, albumin, glucose, insulin, glycated haemoglobin, high-sensitivity C-reactive protein, and lipid parameters;
- use of a pedometer and recording the type, duration, and frequency of physical activity in a diary.

Blood samples are planned at the beginning of the study and after approximately 12 weeks. The volume of blood collected at each sampling will be **5 mL**.

What are the possible benefits?

No direct health benefit can be promised. Participation in the physical activity programme may support an increase in everyday physical activity and help you better understand your own exercise capabilities, but this cannot be guaranteed.

The study results may contribute to future knowledge about physical activity and biological markers of cardiovascular risk in people receiving haemodialysis. They may help to plan further research and care programmes for dialysis patients.

What are the possible risks and inconveniences?

Physical activity

Physical activity may cause temporary fatigue, sweating, muscle or joint pain or stiffness, shortness of breath, dizziness, palpitations, falls, injury, or a temporary worsening of existing symptoms. In people with chronic illnesses, symptoms involving the heart, circulation, or respiratory system may also occur.

To reduce these risks, participants will be assessed with regard to their health status, and the type and intensity of exercise will be individually adjusted. Please stop exercising and promptly inform medical staff or contact the investigator if you experience chest pain or pressure, worsening shortness of breath, fainting, severe dizziness, palpitations, unusual weakness, an injury, or any other concerning symptom.

Blood sampling

Blood samples will be taken by authorised personnel in accordance with standard procedures.

Questions and time commitment

Completing the questionnaire, keeping a physical activity diary, and attending follow-up visits may take time. Some questions concerning your health and lifestyle may feel personal.

Voluntary participation and withdrawal of consent

Participation in the study is voluntary. You may:

- decline participation without giving a reason;
- choose not to answer any question you do not wish to answer; or
- withdraw your consent and stop participating at any time, without giving a reason.

Refusal to participate or withdrawal of consent will not affect the quality, availability, or continuation of your haemodialysis treatment, any other medical services, or your relationship with medical staff.

If you withdraw your consent, the investigator will ask whether they may retain and analyse the data and samples collected before withdrawal, within the scope permitted by applicable law and the decision of the Ethics Committee. You may refuse further use of the material, where this remains possible under the law and considering the stage of anonymisation.

The investigator may also end your participation if this is necessary for safety reasons, if medical contraindications arise, if you no longer meet the eligibility criteria, or if the study is discontinued by the investigator, sponsor, or Ethics Committee.

Confidentiality and data protection

Your personal data and health-related data will be collected in connection with your participation in the study. They will be used only to the extent necessary to conduct the study, monitor safety, analyse the results, verify that the study has been conducted properly, and meet legal obligations.

Your data will be coded. This means that a code, rather than your name and surname, will be used in the research documentation and database. The key linking the code to your identifying information will be stored separately and protected.

The findings may be published in scientific articles, presented at conferences, or used in pooled scientific analyses. However, your name, surname, and any other information that could directly identify you will not be disclosed.

Authorised members of the research team, the Ethics Committee, and relevant regulatory or oversight authorities may access the study documentation where necessary and subject to confidentiality. Your data will be processed in accordance with applicable data-protection legislation.

Data controller: B. Braun Avitum Dialysis Centre, ul. Sienkiewicza 3, 64-300 Nowy Tomyśl, Poland

Data Protection Officer: Marek Łukaszyk

Costs and compensation

No compensation is provided for participation in the study.

Who can you contact?

For questions about the study, its procedures, possible adverse events, or if you wish to withdraw your consent, you may contact:

Principal Investigator: Leszek Niepolski, MD, PhD

Telephone: +48 602 697 585

Study site: B. Braun Avitum Dialysis Centre, ul. Sienkiewicza 3, 64-300 Nowy Tomyśl, Poland

For matters relating to your rights as a study participant, you may contact:

Ethics Committee: Bioethics Committee of Poznań University of Medical Sciences

What should you do now?

Please do not feel pressured to make a decision immediately. After reading this information, you may ask questions. If you decide to participate, you will be asked to sign a separate informed consent form. You will receive a copy of the signed consent form and this Participant Information Sheet.

Thank you for considering participation in this study.