

Informed consent form for participation in a study

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, Nowy Tomyśl, 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

Participant's full name:

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PESEL number / participant identification number:

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confirm that:

1. I have received and read the “Participant Information Sheet” relating to the above study and have been given sufficient time to consider its contents.
2. The investigator or an authorised member of the research team has explained to me, in a manner that I understand, the purpose, procedures, anticipated duration, potential benefits, possible inconveniences, and risks associated with participation in the study. I have had the opportunity to ask questions and have received answers to them.
3. I understand that the purpose of the study is to assess whether a 12-week moderate-intensity physical activity programme is associated with changes in blood sRAGE concentrations in patients receiving maintenance haemodialysis. The study is scientific in nature and does not guarantee any direct health benefit to me.
4. I understand that, after the baseline assessment, I may be randomly assigned in a 1:1 ratio to one of two groups:
 - the **intervention group**, in which, in addition to standard haemodialysis care, I will take part in a 12-week moderate-intensity physical activity programme preceded by education concerning an active lifestyle; or
 - the **control group**, in which I will receive standard haemodialysis care.
5. I understand that assignment to a study group will be random. The randomisation list is computer-generated, and the allocation is concealed until the participant is enrolled in the study. I cannot choose the group to which I will be assigned.

6. I understand that, depending on the group to which I am assigned, participation in the study may include:
- completing a questionnaire regarding my current physical activity, exercise habits, and readiness to change my lifestyle;
 - a clinical assessment at the start of the study and after 12 weeks, including measurements of body weight, height, body circumferences, and blood pressure;
 - collection and analysis of data related to my haemodialysis treatment, including duration of renal replacement therapy, dialysis adequacy, and residual urine output;
 - blood sampling before a scheduled midweek haemodialysis session, after overnight rest and while fasting, for measurement of sRAGE and selected laboratory parameters;
 - receiving a pedometer and keeping a physical activity diary;
 - in the intervention group: participation in health education and completion of an individually tailored physical activity programme for 12 weeks, with a target of at least three activity sessions per week and an energy expenditure of at least 370 MET-minutes per week. Recommended activities may include walking, exercises using resistance bands or medicine balls, stationary or outdoor cycling, and elliptical training, according to my capabilities and following approval by a nephrologist;
 - in the intervention group: face-to-face and/or telephone contacts intended to monitor adherence to the programme.
7. I understand that participation in physical activity may cause temporary fatigue, shortness of breath, sweating, musculoskeletal pain, dizziness, falls, or worsening of existing symptoms. The risk will be minimised through eligibility assessment, adjustment of activity to my abilities, advice to stop exercising if concerning symptoms occur, and supervision by a nephrologist.
8. I understand that blood sampling may be associated with temporary pain, discomfort, bruising, minor bleeding, infection at the puncture site, fainting, or a vasovagal reaction. Samples will be collected by authorised personnel in accordance with standard procedures.
9. I understand that I should promptly inform medical staff or the research team if I experience chest pain, worsening shortness of breath, dizziness, fainting, palpitations, unusual weakness, injury, or any other concerning symptom during or after physical activity.
10. I understand that I may refuse to participate in the study or withdraw my consent at any time, without providing a reason and without any effect on the quality, availability, or continuation of my haemodialysis treatment or my relationship with medical staff.
11. I understand that the investigator may discontinue my participation in the study if this is justified for safety reasons, if medical contraindications arise, if I no longer meet the eligibility criteria, or if the study is terminated by the investigator, sponsor, or Ethics Committee.
12. I consent to the processing of my personal data and medical data to the extent necessary to conduct the study, monitor its safety, analyse the results, and verify the

proper conduct of the study, in accordance with applicable data-protection legislation. My data will be coded, and no information enabling my identification will be disclosed in publications or presentations of the results.

13. I understand that, where necessary for oversight and with due regard to confidentiality, authorised representatives of the sponsor/study site, auditors, relevant authorities, and the Ethics Committee may have access to the study documentation. Such access will be provided in accordance with applicable law.
14. I understand that the study results may be presented in scientific publications, at conferences, or in pooled scientific analyses, but my identity will not be disclosed.
15. I have received the contact details of the Principal Investigator and understand that I may contact him regarding the study, my rights as a participant, and any problems or adverse events.
16. I confirm that I have received one signed copy of this form and the Participant Information Sheet.

Having read and understood the information above, I voluntarily consent to participate in the study described above.

Participant's consent

Participant's full name:

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Participant's signature:

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Date:

Declaration of the investigator / person obtaining consent

I confirm that I have explained to the participant the purpose, procedures, potential benefits, risks, and inconveniences associated with participation in the study. The participant had the opportunity to ask questions, received understandable answers, and voluntarily provided consent before any study procedures were performed.

Full name of investigator / person obtaining consent:

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Position:

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Signature:

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Date:

Contact details

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.