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STUDY DOCUMENT COVER PAGE

Official Title of the Study
"Local and systemic immune and inflammatory protective mechanisms and risk factors in the progression of carotid artery stenosis and aortic aneurysm"

ClinicalTrials.gov Identifier (NCT Number)
Not yet assigned

Type of Document
Patient Information Leaflet

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INFORMATION
"Local and systemic immune and inflammatory protective mechanisms and risk factors in the progression of carotid artery stenosis and aortic aneurysm"
for patients participating in the research study titled

Dear Patient,

Your referring physician has referred you to us because your complaints, symptoms, and the results of your preliminary imaging examinations strongly suggest that your symptoms are caused by arterial disease, and it is highly likely that you will require vascular surgical intervention. Routine examinations include preoperative standard laboratory blood tests, focus screening, and imaging diagnostics (ultrasound, CT).

The aim of our examinations is to obtain a more precise understanding of the inflammatory processes that may contribute to the development of vascular diseases. In our research, we perform more detailed laboratory tests than usual, with particular emphasis on inflammatory and immunological parameters. Focus screening is also more comprehensive, including microbiological analyses of blood, urine, saliva, stool, and tissue samples removed during surgery. The so-called photon counting CT (PCCT) provides lower radiation exposure. It delivers much higher resolution and allows us to obtain a more detailed image of your vascular disease. PCCT can help establish a more accurate diagnosis and plan the surgery more effectively.

If you consent to the examination, the blood draw performed before the surgery does not pose any risk to you and is not associated with significant complications. The blood draw before the surgery is performed through the intravenous cannula inserted for venous access. Blood samples are taken by highly experienced assistants; therefore, no complications are expected during blood collection.

The imaging examinations performed are part of the clinical investigation protocol; the additional MRI and ultrasound examinations do not involve ionizing radiation and do not pose any health risk.

Saliva sampling prior to surgical anesthesia is performed using a swab applied to the oral mucosa; this procedure does not cause you any burden or significant risk.

During anal sampling, following surgical anesthesia, the perianal area around the anus should be wiped with a swab along the separated buttocks, and a sample should be taken from the segment distal to the rectum. Sampling is performed after surgical anesthesia, so it does not pose any burden or significant risk to you. The tissue removed during surgery, from which samples are taken, would otherwise be disposed of as biological waste. The use of the tissue specimen and cells necessary for the study does not involve any extension of your surgery

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The research use of these does not entail any potential complications regarding your health and recovery.
Participation in the study does not provide any financial benefits. Before enrollment in the study, you have the opportunity to ask questions to the healthcare staff and may decline participation.
If you do not consent to participate in the study, the preoperative evaluation and necessary imaging examinations (e.g., US, CT, etc.) will be conducted according to our clinical protocol and standard practice.
During the scientific processing, your personal data will remain unidentifiable; anonymity is fully ensured. The preservation, storage, and use of biological samples for scientific research are carried out in compliance with European Union regulations at the Semmelweis University Biobank and Biobank Register, in an anonymized form. No external individuals are permitted to access the results.

Your data will not be accessible to unauthorized persons beyond the study participants . Throughout the study, we ensure the utmost protection of your personal data and personality rights, in accordance with the principles set forth in the Declaration of Helsinki regarding health-related observations conducted on human subjects.

We kindly request your consent to help advance the effective treatment of patients with arterial diseases.

Thank you for your cooperation!

…….. ……
Date Patient's signature

…… ……...
Name and stamp number of the informing physician Signature

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