RESEARCH NEWS

Better quality of life and risk prevention for people with chronic kidney disease or heart failure

Home testing: A minimally invasive solution for quick and easy determination of blood potassium levels

People being monitored for chronic kidney disease or heart failure often have high levels of potassium in their blood (hyperkalemia) due to impaired renal potassium excretion caused by kidney damage or by medications. But such medications interfere with urinary potassium excretion. This electrolyte imbalance can be life-threatening and thus must be closely monitored. In collaboration with French start-up Ki'tech, researchers at the Fraunhofer Institute for Microengineering and Microsystems IMM want to revolutionize patient monitoring with a minimally invasive solution that measures biomarkers, including potassium, in the subcutaneous interstitial fluid.

Hyperkalemia affects around seven million people in Europe and the United States. It is therefore a common and serious metabolic complication with a significant impact on healthcare systems and must be diagnosed quickly and easily. Hemodialysis patients are particularly at risk of developing hyperkalemia within hours of a dialysis session, with a risk of life-threatening cardiac arrhythmias. Currently, potassium monitoring is not possible on an outpatient basis. This is where the research work of Fraunhofer IMM and the French start-up Ki'tech comes in. The two organizations have been cooperating since 2021, first in the BIMONKI project and then in the BIMONKI 2 project, which are 100% financed by Ki'tech. The aim of this partnership is to facilitate patient monitoring with a minimally invasive solution that tracks biomarkers in the interstitial fluid using a microfluidic patch and an electrochemical sensor, either in spot measurements or in monitoring over several days. The interstitial fluid is located between the blood capillaries and the body's cells, where exchanges between the capillaries and cells take place. It is easily accessible under the skin thanks to jointly developed devices that provide access to small molecular weight (PM) metabolic biomarkers. Their concentration is identical to that in plasma and their monitoring will be facilitated autonomously, and at home with results available in a few minutes and a display of the potassium level on a smartphone, thus establishing proof of concept.

Measure potassium concentration quickly and autonomously at home

Designed as a disposable product, the patch, which measures five to seven centimeters in diameter, is applied to the arm. It is linked to a smartphone app that shows the measurement results. The measured potassium concentration is displayed in real time, allowing patients to monitor it on an ongoing basis. Data is transmitted wirelessly via

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NFC (Near Field Communication) or low-energy Bluetooth. The entire process is fully automated and requires no intervention from the patient.

"Dialysis patients usually have to go three times a week for dialysis, allowing for a two-day break at the weekend. It is during this interdialytic period at the weekend that it is essential for patients to have real-time access to their potassium levels in order to avoid dangerous heart rhythm disorders or even cardiac arrest," explains Dr. Michael Baßler, researcher at Fraunhofer IMM. 'Our goal is to decrease the morbidity and mortality of these patients as well as to improve the quality of their life,' says Sisi Li, a researcher at the IMM and colleague of Dr. Baßler.

Fraunhofer's unique solution is currently under application for several patent protections. It enables anyone at risk of hyperkalemia to measure their potassium levels themselves at home, painlessly and safely, preventing serious complications. This allows them to actively manage their health, for example by adopting an appropriate diet and lifestyle. The app will also send notifications to patients and transmit the data to an orchestration platform, enabling healthcare professionals to take appropriate action based on the observed levels, ranging from simple recommendations to requests to go to the emergency room as soon as possible. In this way, we are contributing to the development of personalized and preventive medicine in this field.

Excellence in the development of microfluidic systems for diagnostics

The team led by Dr Baßler and Dr Li was responsible for developing the hardware, in particular the microfluidic design for interstitial fluid extraction and miniaturized sensors for the measurement process, as well as calibrating the devices. The researchers were able to draw on their extensive experience in the development of microdevices, including MEMS, sensors and lab-on-a-chip devices for microfluidics.

Currently, potassium levels, which are important for health, can only be measured by a time-consuming blood test during scheduled visits to the hospital or doctor's office using laboratory equipment. With the solution from Ki'tech and Fraunhofer, patients and medical staff get immediate and fast results on their smartphones, giving them new freedom in managing their health. The project partners expect that their development will establish a kind of equivalent to the blood sugar test. Currently, this new minimally invasive solution is available as a demonstrator, and clinical trials are expected to begin at the end of the year.

Picture 1: In the future, people with chronic kidney disease will be able to measure their potassium levels independently at home and view the results on their smartphone.

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