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Xenon gas treatment progresses into drug development

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Researchers in the xenon study: Timo Laitio, Antti Saraste, Juhani Airaksinen, Risto O. Roine, Olli Arola, Harry Scheinin, Riitta Parkkola and Ruut Laitio. Credit: Pasi Leino

xenon gas was studied at the Intensive Care Unit (ICU) of Turku

University Hospital, Finland, in 2009-2014 as a treatment for minimising the damage of cardiac arrest, and now it enters drug development in spring 2018. NeuroproteXeon is advancing the study of xenon in a pivotal phase III trial. An earlier study discovered that xenon protects the white matter in the brain from damage, and the latest research showed that xenon can also protect the heart.

The studies showed that xenon protects the brain when patients are treated for cardiac arrest. The results of the study were published in the *Journal of the American Medical Association* in the spring of 2016. In November 2017, a further study was published in the *Journal of American College of Cardiology* demonstrating that xenon can also protect the heart during the intensive care of cardiac arrest patients.

"According to the original publication, patients who inhaled xenon gas, when administered for 24 hours following a cardiac arrest, had notably less damage in their cerebral white matter than the patients in the control group. In addition, the latest results show that xenon reduces the size of infarct in cardiac arrest and thus protects the heart," summarises the leader of the research group, Docent of the University of Turku Timo Laitio, who is a Specialist in anaesthesiology and intensive care at the ICU of Turku University Hospital.

The research results received a great deal of attention after the publication on the use of xenon gas for neuroprotection following a cardiac arrest. The drug development now moves to phase III where the results are tested on a larger group of patients. With positive results from a pivotal phase III study, marketing authorization from regulatory bodies may be pursued. The phase III trial will be conducted in 30 unique sites in North America, Europe, and Australia.

"The earlier research was pioneering work and started from my original idea. The results we received on the promising protective characteristics

of xenon can now be verified in a considerably larger trial with 1,500 patients. The trial will begin in spring 2018 and it investigates whether xenon can be used as a novel treatment in intensive care for the syndrome caused by cardiac arrest, particularly for brain damage and heart injury caused by oxygen deficiency," says Dr. Laitio.

Dr. Laitio is one of the five members of the Trial Executive Committee (TEC) sponsored by NeuroproteXeon.

"We will conduct the observation protocol of the phase III trial according to our own research model. The TEC is responsible for the realisation of and reporting on the project. In addition to the clinical trial, approximately 200 patients will undergo head MRI in approximately ten facilities. Together with the research group lead by Professor Louis Puybasset, we are responsible for the neuroradiology section of the study."

Bill Stoll, Vice President of Regulatory & Quality at NeuroproteXeon added, "The cytoprotective properties of xenon gas have been well received by regulatory scientist at both FDA and EMA. As such, we have an approved phase III protocol to study xenon in Out of Hospital Cardiac Arrest (OHCA) patients in the US and the EU. We believe that xenon gas combined with the Targeted Temperature Management (TTM) can significantly improve OHCA patients survival and neurofunctional outcomes. NeuroproteXeon will continue to develop xenon gas—XENEX for a multitude of neurologic insult events such as stroke and traumatic brain injuries."

Prolonged oxygen deficiency can cause irreversible brain damage as well as injury to the heart and other organs during cardiac arrest. Before the Finnish xenon study, no researched drug was known to protect the brain from damage during oxygen deficiency.

In the ground breaking clinical study conducted in 2009-2014, ICU patients who were resuscitated after a cardiac arrest were given xenon. The main goal of the study was to investigate the effect of xenon on cerebral white matter.

"After the treatment, it was concluded with a head MRI that the patients who received xenon had significantly less damage in their cerebral white matter than those who received ordinary treatment. The study implicates that xenon has a protective effect on humans, as cerebral white matter is especially important for higher intellectual functions," says Dr. Laitio.

Provided by University of Turku

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