NovaSignal Announces First Patient Enrolled in Innovative Clinical Trial

LOS ANGELES, CA (Oct. 13, 2020) -- NovaSignal Corp., a medical technology and data company specializing in assessing cerebral blood flow, today announced enrollment of the first patient in its clinical trial evaluating the advantages of the NovaGuide Intelligent Ultrasound in detecting a patent foramen ovale (PFO) compared to traditional ultrasound methods. A PFO, more commonly known as a hole in the heart, is a congenital abnormality impacting approximately 25% of the entire population and is a known risk factor for stroke. Across the globe 500,000 strokes occur every year in patients suspected of having a PFO. Without detection and treatment, those patients are at significant risk of having another stroke leading to permanent disability or death.

A procedure known as a bubble study, where bubbles are injected into the bloodstream and monitored via ultrasound, is used to detect a PFO. Transthoracic echocardiography (TTE) is the most frequently used non-invasive ultrasound technique, though it provides low diagnostic sensitivity (45.1%). Transcranial Doppler ultrasound (TCD) has shown high diagnostic sensitivity but delivers inconsistent results due to the inherent variability of conducting the exam manually.[1]

The NovaGuide addresses the shortcomings of both TTE and TCD through advanced machine learning algorithms and robotic technology. NovaGuide delivers high reliability, consistent measurements, and gold-standard sensitivity (96.1%). Designed to autonomously locate major blood vessels and assess blood flow, the FDA-cleared NovaGuide is the only fully automated, AI-driven cerebral ultrasound system available.

The primary objective of the trial, named BUBL, is to evaluate the PFO detection rate of the NovaGuide vs standard of care diagnostic techniques. The BUBL trial is a prospective, single-arm, non-significant risk (NSR) device study. Up to 200 patients across six US sites with suspicion of embolic stroke of unknown origin will be evaluated with the NovaGuide and TTE.

“The accuracy of transcranial Doppler ultrasound in detection of left to right shunts such as PFO is well known but performing these exams manually can be challenging. We are excited to start this trial to evaluate a robotic system compared to the traditional standard of care,” said Andrei V. Alexandrov, MD, Semmes-Murphey Professor, and Chairman of the Department of Neurology at The University of Tennessee Health Science Center.

“With nearly half a million people at risk of having a second stroke due to a PFO, there is a clear need for reliable and accurate diagnostic tools. I believe this study will show that by combining AI, robotics, and automated cerebral ultrasound, NovaGuide is revolutionizing how brain health data

[1] Katsanos, A. H., Psaltopoulou, T., Sergentanis, T. N., Frogoudaki, A., Vrettou, A. R., Ikonomidis, I., … Tsivgoulis, G. (2016). Transcranial Doppler versus transthoracic echocardiography for the detection of patent foramen ovale in patients with cryptogenic cerebral ischemia: A systematic review and diagnostic test accuracy meta-analysis. *Annals of Neurology*, *79*(4), 625–635. https://doi.org/10.1002/ana.24609

is harnessed and ultimately transforming patient care." said Robert Hamilton, Co-Founder and Chief Scientific Officer of NovaSignal.

About NovaSignal

Founded in 2013, NovaSignal Corp. is a medical technology company whose mission is to save lives by unlocking the hidden power of blood flow data. The company's FDA-cleared NovaGuide Intelligent Ultrasound combines non-invasive ultrasound, robotics, and artificial intelligence to assess real-time cerebral blood flow. Using cloud computing and data analytics, NovaSignal supports physicians in their clinical decision making of diseases identified through cerebral blood flow. This includes strokes, intra-cardiac shunts, and intra-pulmonary shunts (as recently demonstrated with patients suffering from COVID-19).

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