

Therapeutic Hypothermia After Cardiac Arrest with Non-Shockable Rhythm (HYPERION) Shows Statistically Significant Results In Cardiac Arrest Patients Presented At AHA

The HYPERION study was published in New England Journal of Medicine (NEJM) on October 5, 2019, with a first simultaneous presentation at the ESICM meeting in Berlin, Germany. The study was also presented and discussed at the ReSS meeting, part of the American Heart meeting in Philadelphia on Nov 16, 2019 as a special presentation by the Principal Investigator (PI) of the trial, Dr. Jean-Baptiste Lascarrou. Although, BrainCool was not part of the study, the results will have a large impact on the development of the temperature management market.

In 2013, Targeted Temperature Management (TTM) Trial showed that cooling to 33°C after cardiac arrest did not improve survival or neurologic outcomes compared to cooling to 36°C. (The findings of that trial have been challenged on the basis that many patients were not cooled quickly.) Since cooling to 36°C is easier than to 33°C, it has become a widespread practice in the U.S. after cardiac arrest, especially for shockable rhythms (ventricular tachycardia or fibrillation). However, only about 20% of patients in the TTM trial had non-shockable rhythms.

Hyperion (randomized, multi-center trial) was designed to investigate the effect of therapeutic temperature management at 33°C or 37°C in this group of patients with non-shockable cardiac arrest. The study conducted in 25 French intensive care units (ICUs), showed a statistical significance in favor of hypothermia treatment in non-shockable patients (**n=584**). The primary result was positive: more patients in the hypothermia group had a favorable neurologic status at day 90 (10.2% vs. 5.7%, $p=0.047$), the result being statistically significant.

CEO Martin Waleij comments;

- The clinical results of the Hyperion study open up the hypothermia market in this segment, as this is the largest study population in this very seriously ill patient group showing statistically significant results. Besides the statistically significant results, there is yet further evidence that 33 degrees as target temperature leads to improved results.

Although BrainCool was not part of this study, it opens up to further implementation of temperature management.

Some factors worth highlighting when comparing the Princess study with the Hyperion study:

- The patient population in the Hyperion study was selected and randomized from patients admitted alive to hospital. In these patients group a number of patients randomized in the Princess trial did die before even reaching to the hospital.
- Time from randomization to target temperature (33°C) was about 317 minutes in the Hyperion trial. This can be compared with the Princess trial of 101 minutes in the active group and even 182 minutes in the control group. Also, randomization in the Princess trial was completed in average in 17 minutes after collapse compared with the Hyperion trial, in which if considering the time before randomization (300 min max), the total time from collapse and to target would be up to ~600 min (~10 hours). As such, it might be worth emphasizing that the BrainCell concept (RhinoChill™ System + BrainCool™



System for both out of the hospital as well as in-hospital) could potentially save 8 hours on an average in a very early phase even when applied only in the hospital, as compared to Hyperion study.

During the question session the Head of the GRC, Professor Bernd Boettiger, Department of Anesthesiology and Intensive Care Medicine, University of Cologne, discussed the long time to reach target temperature in the trial, up to 5 – 6 hours after randomization and the conclusion was that an earlier implementation of cooling would give a high likelihood of substantially improved results.

For more information

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About BrainCool AB (publ)

BrainCool AB (publ) is an innovative medical device company that develops, markets, and sells leading medical cooling systems for indications and areas with significant medical benefits within the healthcare sector. The company focuses on two business segments, Brain Cooling and Pain Management. BrainCool AB (publ) is based in Lund, Sweden, and its share is listed on Spotlight Stock Market.