

Karolinska starts the clinical study PRINCESS 2 with BrainCool's product RhinoChill® System

BrainCool AB (publ) can today announce that Karolinska Institutet/University Hospital tomorrow (March 27th) will start the recruitment of patients for the large and groundbreaking clinical study PRINCESS 2, which is based on BrainCool's product RhinoChill® System. RhinoChill® System enables a unique cooling method for early and ultra-fast cooling of the brain.

This means that as of tomorrow, a number of Swedish physician manned emergency vehicles (Sw. Akutläkarbilar) are equipped with BrainCool's product RhinoChill® System. Thus, RhinoChill® System is now used in practice for acute treatment of cardiac arrest in the daily Swedish emergency care within the framework of this study. As soon as one of the equipped vehicles reaches a patient with cardiac arrest, the patient will be treated with RhinoChill® System.

ABOUT THE PRINCESS 2 STUDY

PRINCESS 2 is a randomized international clinical trial involving approximately 1,000 patients. The study is led by Karolinska Institutet/University Hospital. A further 20 or so European clinics in Italy, Spain and Germany, among others, will participate. The aim of the study is to evaluate the effect of early and ultrafast cooling in the treatment of patients who have suffered cardiac arrest. Efficacy is measured as survival and recovery of neurological function.

Per Nordberg, senior consultant at Karolinska University Hospital and principal investigator of PRINCESS 2, comments:

-" The project is unique in the world and involves highly specialized care with cooling already at the site of the cardiac arrest or in an emergency vehicle and then continues upon arrival at the hospital."

BrainCool's CEO Jon Berg comments:

-"We feel both joy and pride that BrainCool has reached yet another new milestone by participating in a large international clinical study where RhinoChill® System plays a central role. The fact that PRINCESS 2 is now starting confirms that we are at the forefront of medical cooling and technological expertise. If the study is successful, it means a great economic potential for BrainCool."

BrainCools Head of Clinical Studies Mohammad Fazel comments:

-"Unlike previous studies, PRINCESS 2 focuses on early and rapid cooling at the scene of a cardiac arrest. RhinoChill® System is specially developed for fast cooling, and as it is portable, it can be used flexibly and deployed quickly in different situations".

This entire clinical study is run by Karolinska Institutet and thus does not burden BrainCool financially. Instead, BrainCool receives revenue by delivering products to the study and the order value amounts to approximately SEK 3 million during the duration of the project. The study may form the basis for formal approval of the treatment of early and ultrafast cooling in cardiac arrest as a medical indication.

ABOUT RHINOCHILL® SYSTEM

RhinoChill® System is a portable cooling system for cooling the brain via the nasal cavities. Early and ultra-fast cooling of the brain is achieved, which, according to the study's hypothesis, significantly reduces the risk of the patient dying or suffering from neurological impairments as a result of the cardiac arrest.

The system includes disposable products in the form of coolants and catheters, which means great potential for ongoing sales for each treated patient.

RhinoChill® System can also be used in hospitals for the treatment of stroke associated with thrombectomy (i. e. removal of a blood clot in the brain), within the framework of another study, COTTIS II. Thus, RhinoChill® System has two different areas of use that are now being evaluated in the studies PRINCESS 2 (cardiac arrest) and COTTIS II (stroke).

ABOUT CARDIAC ARREST

Approximately five million people globally suffer from cardiac arrest annually, of which about 20 percent survive. Direct health and care costs are estimated at SEK 1.2 million per patient in the United States, according to a study "[Health Care Costs After Cardiac Arrest in the United States | Circulation: Arrhythmia and Electrophysiology](#)" ([ahajournals.org](#)). With early and ultra-fast cooling, survival rates can increase and lead to fewer or no neurological impairments, which means reduced suffering for the patient while there are significant health economic gains.

Contact**For more information**

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About Us

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. BrainCool AB (publ) is based in Lund, Sweden, and its share is listed on Nasdaq First North Growth Market, named "BRAIN".

Eminova Fondkommission AB is the company's Certified Adviser.

This information is information that BrainCool is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-03-26 16:39 CET.

Attachments

[Karolinska starts the clinical study PRINCESS 2 with BrainCool's product RhinoChill® System](#)