

# BeneChill News Release



## RhinoChill IntraNasal Cooling System Rapidly and Effectively Reduces Brain Temperature in Neurologically Injured Patients

Results from new study of stroke, ICH and trauma patients published in *Stroke*

**26 July 2011** – A new portable system which cools the brain via the nasal cavity has been demonstrated effective and safe in patients with neurological injury where therapeutic hypothermia was indicated. In a new study just published in the prestigious peer-reviewed journal *Stroke*<sup>1</sup>, the RhinoChill® IntraNasal Cooling System was shown to rapidly and effectively cool the brains of patients with neurological injury caused by stroke, intra-cerebral hemorrhage (ICH) or trauma. This was the case even in patients with a fever. There were no unanticipated adverse events or nasal complications.

The prospective, single-arm study involved a total of 15 patients with brain injury caused by ischemic stroke, ICH or head trauma in equal numbers, where therapeutic hypothermia was indicated. In nine patients this was for fever control, and in the remaining six for neuroprotection or control of intracranial pressure (ICP). Following rhinoscopy, the RhinoChill system was used exclusively for at least an hour in all patients except one to initiate temperature reduction, after which standard cooling methods were administered according to local procedures. After this first hour brain, tympanic and core body temperatures were measured.

Brain, tympanic and core body temperatures were reduced by averages of 1.4 degrees, 2.2 degrees and 1.1 degrees respectively at this point. All patients showed a temperature reduction of at least 0.2 degrees centigrade within 15 minutes, and 13 patients (87%) achieved a brain or tympanic temperature reduction of at least one degree or more after one hour.

Reductions in all three temperature readings were as great in the febrile patients as they were in afebrile ones. There was only one device-related adverse event: transient hypertension that resolved with removal of the RhinoChill System in the only patient not cooled for at least an hour.

“It is becoming well-established that rapid, effective brain cooling provides a valuable neuroprotective effect in patients with brain injury”, commented the study’s principle investigator Dr Alex Abou-Chebl, Associate Professor of Neurology,

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University of Louisville School of Medicine, USA. “But what we really need is a better way of achieving this. Results from this study suggest that the RhinoChill IntraNasal Cooling System can rapidly and effectively reduce brain temperature in neurologically-injured patients as an adjunct to conventional cooling methods.”

“The RhinoChill System has the potential to lower brain temperature more rapidly and effectively than external cooling, and more conveniently and less invasively than internal cooling methods”, added study investigator Dr Denise Barbut, a neurologist who founded BeneChill specifically to develop methods of rapid, effective brain cooling. “This study also suggests that it can be effective even in febrile patients with an elevated brain temperature. It will also work in patients with a large body mass, where whole-body cooling methods will simply not be effective.”

#### **More/...**

Therapeutic hypothermia is well established as an effective neuroprotectant following cerebral ischemia, but conventional methods have their drawbacks; external cooling methods can be laborious, and brain cooling can take some time as the body's periphery and core have to cool first. Internal cooling methods can be more effective and rapid-acting than surface cooling, but are invasive and still require core body cooling before brain temperature reduction can be achieved.

The RhinoChill System is quick to set up and extremely easy to use. It uses a non-invasive nasal catheter that sprays a rapidly evaporating, inert coolant liquid into the nasal cavity, a large area situated beneath the brain that acts as a heat exchanger. As the liquid evaporates, heat is directly removed from the base of the skull and surrounding tissues via conduction and indirectly through the blood via convection.

A European clinical study<sup>2</sup> in cardiac arrest patients has shown that when administered by Emergency Medical System (EMS) personnel as soon as they reach a victim and continued during transport to hospital, the RhinoChill System effectively reduces body temperature by the time the victim reaches the hospital. Survival without loss of brain function was significantly improved in patients where resuscitation procedures and subsequent RhinoChill cooling were initiated within ten minutes of cardiac arrest, compared with patients who were not cooled in the pre-hospital setting.

The RhinoChill® IntraNasal Cooling System is now available in major European markets following CE Mark approval for inducing therapeutic hypothermia immediately following cardiac arrest.

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**About BeneChill, Inc.**

BeneChill is a medical device company based in San Diego, California, with European headquarters in Lausanne, Switzerland. The company is developing products in the therapeutic hypothermia arena with a focus on rapid, non-invasive cooling for use in the field. The RhinoChill System is limited by U.S. law to investigational use only. For more information, go to [www.benechill.com](http://www.benechill.com)

**References:**

1. Abou-Chebl A, Sung G, Barbut D, Torbey M. Local brain temperature reduction through intranasal cooling with the RhinoChill device: preliminary safety data in brain injured patients. *Stroke* 2011; **42**: 2164-2169.
2. Castren M, Nordberg P, Svensson L et al. Intra-arrest transnasal evaporative cooling: a randomized, pre-hospital, multicenter study (PRINCE: Pre-ROSC IntraNasal Cooling Effectiveness). *Circulation* 2010; **122**: 729-736.