BrainCool AB (publ) signs Clinical Trial Agreement and obtains ethics approval for a Dutch multicenter trial with severe migraine patients in hospital

Lund, Sweden March 6, 2017

BrainCool AB has signed a clinical trial agreement ("CTA") for a multicenter clinical trial at four centres, to be led by Principal Investigator Hille Koppen, MD, neurologist from the neurology department, Haga Teaching Hospital.

The clinical trial, which now has received ethics approval, is a prospective, double-blinded, sham-controlled, randomized controlled trial. Eighty patients are to be enrolled with 40 receiving the active treatment, and 40 receiving the sham. The clinical trial will investigate the analgesic effect of our novel non-pharmacological treatment, used to relieve the symptoms of severe withdrawal headache in adult patients with triptan overuse headache, who are admitted to hospital for a period of detoxification.

Migraine affects approximately one in eight people. A significant minority of this group, up to 5 % of the population, as a whole, suffer from chronic migraine, defined as 15 or more days of headache per month.

Medication overuse headache (MOH) is a disorder that results from the overuse of analgesics, triptans or other acute headache medication. Triptans are a class of drug that are used as migraine rescue medication to attempt to abort migraine in the early stages of an attack. Patients overusing triptans are almost always patients with migraine as their primary headache.

There is general agreement that the only treatment of MOH is withdrawal of the overused medication (i.e. detoxification).

Discontinuation of the overused headache medication often results in the development of withdrawal headache, often associated with nausea, vomiting, photophobia, phonophobia, sleep disturbances, restlessness and nervousness.

In general, and especially in the case of triptan overuse, the first week of detoxification is most difficult. This results in the frequent failure of the detoxification process and subjects continuing to overuse their medication. Today, management of withdrawal headache is based on symptom palliation and no direct alternative treatment for withdrawal headache during triptan detoxification exists.

The objective of this study is to investigate the effect of the RhinoChill® System, from BrainCool AB, on severity and frequency of withdrawal headache and associated symptoms in the first 7 days (as an adjunct) during standard care treatment for detoxification of triptan-overuse headache as compared to adjunctive sham treatment during standard care.

This study is an investigator led clinical trial, with no direct funding from BrainCool AB, however devices are provided for the use in the clinical trial.

Principal Investigator Hille Koppen, MD, Neurologist, neurology department, Haga Teaching Hospital, comments;

Triptan overuse headache occurs in up to 5% of migraine patients globally, resulting in severe headaches that are actually caused by the use of triptans. Instead of helping these patients abort migraine attacks, they instead become dependent on their triptans.

The only solution is to stop the use of triptans, just like most other treatment strategies in addiction/dependence.

No other pain medications are allowed during this period, so these patients will face symptoms of detoxification, including severe withdrawal headaches as well as their original migraine attacks, for which they cannot use any treatment.

Many patients therefore will not succeed in stopping their overuse.

The possibility of an effective non-pharmacological treatment to control the pain of withdrawal headache and the associated symptoms in this patient group is a game changer. If proven effective, the use of RhinoChill® in the hospital could provide much needed relief and symptom control, and could help patients succeed in this detoxification period.

Martin Waleij CEO BrainCool AB comments;

With this investigator led clinical trial, we are following up the favourable and exciting results from the first clinical trial with the RhinoChill® (CoolHead 1) device in a hospital setting. We will investigate if the application of RhinoChill® nasal cavity cooling will provide effective relief of withdrawal headache and associated symptoms in patients with triptan-overuse headache in the first week of in hospital detoxification.

This trial is of high academic and clinical impact and could also be an important competition benchmark versus the pharma products in the migraine market place.

In addition to providing first evidence of an effective non pharma treatment for triptan overuse headache detoxification, the resulting clinical evidence will further support the initial results of the COOLHEAD 1 pilot trial and create a base for a possible ‘at home’ nasal cavity cooling therapy for acute episodic migraine in addition to the evidence for the hospital treatment market.

In the completed and published COOLHEAD 1 trial in the Journal of Headache and Pain (highly accessed), the use of RhinoChill® nasal cavity cooling within a clinical environment for 15 patients was found to provide a statistically significant reduction of pain and associated symptoms of migraine at 5 minutes and 10 minutes (during treatment), and at 1 hour and 2 hours following treatment (all p values <0.001) along with a significant effect on pain and symptoms at 24 hours ($p <0.001$). In total, 87% of patients enrolled into the trial received a treatment benefit following from a short term (<20 minutes) period of nasal cavity cooling.

For further information

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This press release is submitted both in English and Swedish, in case of any discrepancies, the English version will apply.