**A randomised pilot study comparing conventional brain cooling with additional trans-nasal cooling prior to and during ascending aorta/proximal aortic arch surgery - ARcTIC-1.**

**Abstract:**

**Background:**

Aortic arch replacement is associated with postoperative neurocognitive complications, which can be multifactorial. Deep Hypothermic Circulatory Arrest (DHCA) may be used to protect the brain. We investigated the use of additional trans-nasal brain cooling prior to and during proximal aortic arch surgery in order to determine whether this reduces the incidence and/or severity of postoperative cognitive impairment.

**Methods:**

A total of 19 patients were recruited to this prospective randomised pilot study between March 2014 and March 2016. Patients in the control group underwent systemic cooling to 15°C prior to the onset of circulatory arrest. The intervention group received additional trans-nasal cooling commencing before the start of the surgical incision. All anaesthetic techniques and medications were standardised for both groups.

**Results:**

Similar demographics were observed for both groups. No significant difference was observed between the two groups for the Intensive Care Delirium Screening Checklist and the Six-item Cognitive Impairment Test post-operatively.

**Conclusion:**

This is the first study to explore the use of trans-nasal brain cooling in proximal aortic arch surgery. No significant difference was identified in this pilot study between the two groups.

**Summary of results:**

Nineteen patients were randomised: ten to the intervention group and nine to the control group. One patient, who had been randomised to the intervention group, was withdrawn as the second study centre chose not to participate due to issues in their department. One patient, who had been randomised to the intervention group, was withdrawn due to having a deformed nasal septum which would not allow safe insertion of the nasal cooling probe. Therefore, data from 17 patients was analysed: eight in the intervention group and nine in the control group.

**Post-operative variables:**

One patient in the intervention group died on the eighth postoperative due to multiorgan failure. Hence the intervention group postoperative data analysis consisted of seven patients. One patient in the intervention group developed a stroke as he was already had a history of stroke and TIA pre-surgery. One patient in the intervention group required re-sternotomy for bleeding and one patient required a tracheostomy. There was no requirement for early discontinuation of nasal cooling for any patient in the intervention group.

**Intensive Care Delirium Screening Checklist (ICDSC) scores:**

Three patients in the intervention group were ventilated on day 1 and as such had no total shift score, hence the scores for five patients in the intervention group were collected on day 1 and six patients on day 2. No difference was observed between the groups for each day.

**Six-item Cognitive Impairment Test (6CIT) scores:**

6CIT scores were obtained pre and postoperatively for each patient. Scores of 0 were observed for all patients pre-operatively. A median score of 0 was observed at all follow-up time points with the exception of the day 1 morning score. All patients had a score of 0 by day 6.

So, we can conclude that, although some patients did show signs of post-operative confusion, once transferred to the ward environment the median 6CIT score for both groups of patients was 0 and no patients in either group had any evidence of persistent delirium by ward on day 6. There was no evidence of confusion at the 30 day follow up.

**Length of hospital stay:**

The median total hospital stay was 8 days and there was no significant difference between the groups.

**Adverse events:**

Two out of 17 patients experienced serious adverse events, both of which were in the intervention group. One patient developed stroke and one patient died. Following this death, the study was stopped and investigated by an independent research committee who concluded that it was not known whether there was a relationship between the event and the use of Rhino Chill equipment.