

# Hyperbaric oxygen in the treatment of acute ischemic stroke. A double-blind pilot study.

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**BACKGROUND AND PURPOSE:** The effects of hyperbaric oxygen (HBO) therapy on humans are uncertain. Our study aims first to outline the practical aspects and the safety of HBO treatment and then to evaluate the effect of HBO on long-term disability.

**METHODS:** Patients who experienced middle cerebral artery occlusion and were seen within 24 hours of onset were randomized to receive either active (HBO) or sham (air) treatment. The HBO patients were exposed daily to 40 minutes at 1.5 atmospheres absolute for a total of 10 dives. We used the Orgogozo scale to establish a pretreatment functional level. Changes in the Orgogozo scale score at 6 months and 1 year after therapy were used to assess the therapeutic efficacy of HBO. In addition, we used the Rankin scale and our own 10-point scale to assess long term-disability at 6 months and 1 year. Two sample t tests and 95% confidence intervals were used to compare the mean differences between the two treatment groups. Student's two-tailed test was used to compare the differences between pretherapeutic and posttherapeutic scores at 6 months and 1 year in the two treatment groups. **RESULTS:** Over the 3 years of study enrollment, 34 patients were randomized, 17 to hyperbaric treatment with air and 17 to hyperbaric treatment with 100% oxygen. There was no significant difference at inclusion between groups regarding age, time from stroke onset to randomization, and Orgogozo scale scores. Neurological deterioration occurred during the first week in 4 patients in the sham group, 3 of whom died; this worsening was clearly related to the ischemic damage. Treatment was also discontinued for 3 patients in the HBO group who experienced myocardial infarction, a worsening related to the ischemic process, and claustrophobia. Therefore, 27 patients (13 in the sham group and 14 in the HBO group) completed a full course of therapy. The mean score of the HBO group was significantly better on the Orgogozo scale at 1 year ( $P < .02$ ). However, the difference at 1 year between pretherapeutic and posttherapeutic scores was not significantly different in the two groups ( $P < .16$ ). Moreover, no statistically significant improvement was observed in the HBO group at 6 months and 1 year according to Rankin score ( $P < .78$ ) and our own 10-point scale ( $P < .50$ ). **CONCLUSIONS:** Although the small number of patients in each group precludes any conclusion regarding the potential deleterious effect of HBO, we did not observe the major side effects usually related to HBO. Accordingly, it can be assumed that hyperbaric oxygen might be safe. We hypothesize that HBO might improve outcome after stroke, as we detected an outcome trend favoring HBO therapy. A large randomized trial might be required to address the efficacy of this therapy.

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