

<http://hboevidence.unsw.wikispaces.net/Mathai>

Improvement in gross motor function measure following a long course of hyperbaric oxygenation in children with cerebral palsy.

Clinical bottom line:

1. Some indication of benefit from HBOT with cerebral palsy in respect to gross motor function measures.
2. No clear benefit for either spasticity or speech scores, or SPECT findings.
3. Very small study which has not been peer reviewed.

Citation/s: 1. Mathai SS, Bansali P, Singh Gill B, Nagpal S, John MJ, Aggarwal H, Bhatt V. Effects of hyperbaric oxygen therapy in children with cerebral palsy. Proceedings of the International Conference on Diving and Hyperbaric Medicine, Barcelona 7-10 September 2005:193-197.

Three-part Clinical Question: In children with cerebral palsy, does hyperbaric oxygen improve function?

Search Terms: Cerebral palsy

The Study: Double-blinded randomised controlled trial with intention-to-treat.

The Study Patients: Children with cerebral palsy aged 1 to 10 years and able to attend chamber over several months.

Control group (N = 9; 9 analysed): Compression to 1.5 ATA breathing air for one hour daily for 5 weeks (30 treatments). Repeated 3 times with one month interval (total 90 treatments).

Experimental group (N = 11; 11 analysed): As above, but breathing 100% oxygen.

The Evidence:

Outcome	Time to Outcome	Sham rate	HBOT rate	Relative risk reduction	Absolute Risk Reduction	NNT
Improvement in upper limb spasticity score	One month	0.333	0.364	9%	0.03	32
	95% Confidence Intervals:			135% to -100%	0.45 to -0.39	NNT = 2 to INF; NNH = 3 to INF
Improvement in lower limb spasticity score	One month	0.222	0.455	105%	-0.23	4
	95% Confidence Intervals:			285% to -75%	0.63 to -0.17	NNT = 2 to INF; NNH = 6 to INF
Improved SPECT scan	One month	0.222	0.545	145%	0.32	3
	95% Confidence Intervals:			326% to -35%	0.72 to -0.08	NNT = 1 to INF; NNH =

Measure	Sham Group		HBOT Group		Difference	95% CI
	Mean	SD	Mean	SD		
Mean change in gross motor function measure	5.8	2.9	14.6	4.2	8.8	12.3 to 5.3

Non-Event Outcomes	Time to outcome/s	Control group	Experimental group	P-value
Change in speech score	One month	pre: 2.0 +/- 0.7 post: 2.4 +/- 0.8	pre: 2.2 +/- 0.5 post: 3.1 +/- 0.5	>0.05 <0.05

Comments:

1. No sample size calculation and this study has very low power to detect even quite large differences between groups.
2. Given the method of randomisation by sealed envelopes, it is not clear why the groups are not equal in numbers.
3. Long course of HBOT is unusual - 90 treatments over six months.
4. No plausible mechanism of action and the authors imply that most cases of CP are due to hypoxia in the perinatal or early postnatal period, rather than developmental in aetiology.
5. Many potentially important confounders have not been considered (e.g. Apgar scores, prematurity) and there is a strong possibility of bias given the small numbers.

6. Clinical significance of the improvement in GMFM requires expert interpretation.

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