

# INOMAX® (nitric oxide) gas, for inhalation Reference Bibliography

This bibliography contains verifiable peer-reviewed manuscripts and abstracts on the use of INOmax in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. Human studies, health economic and outcomes analyses (HEOR), reports are included and, where available, links to PubMed are provided. Updated: August 2020

# **Prospective Studies**

- 1. Inhaled nitric oxide in full-term and nearly full-term infants with hypoxic respiratory failure. The Neonatal Inhaled Nitric Oxide Study Group. *N Engl J Med.* 1997;336(9):597-604. Link.
- 2. Ahearn J, Panda M, Carlisle H, Chaudhari T. Impact of inhaled nitric oxide stewardship programme in a neonatal intensive care unit. *J Paediatr Child Health*. 2020: 56(2):265-271 <u>Link</u>.
- Al Omar S, Salama H, Al Hail M, Al Rifai H, Bunahia M, El Kasem W, Siddiqui FJ, Dilawar M, Yassin H, Masud F, Mohamed A, Mansour A. Effect of early adjunctive use of oral sildenafil and inhaled nitric oxide on the outcome of pulmonary hypertension in newborn infants. A feasibility study. J Neonatal-Perinat Med. 2016;9(3):251-259. <u>Link</u>
- 4. Barefield ES, Karle VA, Phillips JB 3rd, Carlo WA. Inhaled nitric oxide in term infants with hypoxemic respiratory failure. *J Pediatr*. 1996;129(2):279-86. <u>Link</u>.
- Christou H, Van Marter LJ, Wessel DL, et al. Inhaled nitric oxide reduces the need for extracorporeal membrane oxygenation in infants with persistent pulmonary hypertension of the newborn. Crit Care Med. 2000;28(11):3722-7. Link.
- 6. Clark RH, Kueser TJ, Walker MW, et al. Low-dose nitric oxide therapy for persistent pulmonary hypertension of the newborn. Clinical Inhaled Nitric Oxide Research Group. *N Engl J Med.* 2000;342(7):469-74. Link.
- 7. Cornfield DN, Maynard RC, deRegnier RA, Guiang SF, Barbato JE, Milla CE. Randomized, controlled trial of low-dose inhaled nitric oxide in the treatment of term and near-term infants with respiratory failure and pulmonary hypertension. *Pediatrics*. 1999;104(5):1089-94. Link.
- 8. Dadiz R, Nair J, D'Angio CT, Ryan RM, Lakshminrusimha S. Methemoglobin and the response to inhaled nitric oxide in persistent pulmonary hypertension of the newborn. *J Neonatal Perinatal Med.* 2020;13(2):175-182. <u>Link</u>
- Davidson D, Barefield ES, Kattwinkel J, et al. Inhaled nitric oxide for the early treatment of persistent pulmonary hypertension of the term newborn: A randomized, double-masked, placebocontrolled, dose-response, multicenter study. The I-NO/PPHN study group. *Pediatrics*. 1998;101(3 Pt 1):325-34. <u>Link</u>.
- Fakioglu H, Totapally BR, Torbati D, Raszynski A, Sussmane JB, Wolfsdorf J. Hypoxic respiratory failure in term newborns: Clinical indicators for inhaled nitric oxide and extracorporeal membrane oxygenation therapy. *J Crit Care*. 2005;20(3):288-293. <u>Link</u>.
- 11. Khan F, Moya F, Khan AM. The relationship between thromboxane and prostacyclin levels and response to inhaled nitric oxide therapy in neonates with hypoxemic respiratory failure: A pilot study.[WSMRF abstract 410]. *J Invest Med.* 2005;53(1):S326.
- 12. Kinsella JP, Neish SR, Shaffer E, Abman SH. Low-dose inhalation nitric oxide in persistent pulmonary hypertension of the newborn. *Lancet.* 1992;340(8823):819-20. <u>Link</u>.
- 13. Konduri GG, Solimano A, Sokol GM, et al. A randomized trial of early versus standard inhaled nitric oxide therapy in term and near-term newborn infants with hypoxic respiratory failure. *Pediatrics*. 2004;113(3):559-64. Link.
- 14. Roberts JD, Polaner DM, Lang P, Zapol WM. Inhaled nitric oxide in persistent pulmonary hypertension of the newborn. *Lancet*. 1992;340(8823):818-9. <u>Link</u>.
- 15. Tworetzky W, Bristow J, Moore P, et al. Inhaled nitric oxide in neonates with persistent pulmonary hypertension. *Lancet*. 2001;357(9250):118-20. Link.



### **Retrospective Studies**

- Bondi D, Shah P, Hussain W, Barlett A, Knoebel R, Morgan S, Mosakowski S, Orr R, Parker B, Singh J, Schreiber M. Inhaled nitric oxide stewardship in the neonatal intensive care unit. [ACCP abstract 338] *J Am Coll Clin Pharm.* 2018;1(2):247.
- 17. Coates EW, Klinepeter ME, O'Shea TM. Neonatal pulmonary hypertension treated with inhaled nitric oxide and high-frequency ventilation. *Journal of Perinatology*. 2008;28(10):675-9. Link.
- 18. Golombek SG, Young JN. Efficacy of inhaled nitric oxide for hypoxic respiratory failure in term and late preterm infants by baseline severity of illness: A pooled analysis of three clinical trials. *Clin Ther.* 2010;32(5):939-48. Link.
- 19. Kayton A, Timoney P, Vargo L, Perez JA. Current practices and attitudes regarding use of inhaled nitric oxide in the NICU: results from a survey of members of the national association of neonatal nurse practitioners. *Adv Neonatal Care*. 2018;18(2):88-97. <u>Link</u>
- 20. Lawrence KM, Monos S, Adams S, Herkert L, Peranteau WH, Munson DA, Hopper RK, Avitabile CM, Rintoul NE, Hedrick HL. Inhaled nitric oxide is associated with improved oxygenation in a subpopulation of infants with congenital diaphragmatic hernia and pulmonary hypertension. J Pediatr. 2020;219:167-172. Link
- 21. Lowe CG, Trautwein JG. Inhaled nitric oxide therapy during the transport of neonates with persistent pulmonary hypertension or severe hypoxic respiratory failure. *Eur J Pediatr*. 2007;166(10):1025-31. Link.
- Morel AA, Shreck E, Mally PV, Kim Y, Bailey SM, Wachtel EV. Clinical characteristics and factors associated with term and late preterm infants that do not respond to inhaled nitric oxide (iNO). J Perinat Med. 2016;44(6):663-668. Link
- 23. Nelin LD, Potenziano JL. Inhaled nitric oxide for neonates with persistent pulmonary hypertension of the newborn in the CINRGI study: time to treatment response. *BMC Pediatrics*. 2019;19(1):1-7. <a href="Link"><u>Link</u></a>
- 24. Sahni R, Ameer X, Ohira-Kist K, Wung JT. Non-invasive inhaled nitric oxide in the treatment of hypoxemic respiratory failure in term and preterm infants. *J Perinat*. 2017;37(1):54-60. Link

### **Case Reports**

25. Kelly LK, Porta NF, Goodman DM, Carroll CL, Steinhorn RH. Inhaled prostacyclin for term infants with persistent pulmonary hypertension refractory to inhaled nitric oxide. *J Pediatr*. 2002;141(6):830-2. Link.

### **Outside of United States Studies**

- 26. Chotigeat U, Khorana M, Kanjanapatakul W. Outcome of neonates with persistent pulmonary hypertension of the newborn treated with inhaled nitric oxide. *J Med Assoc Thailand*. 2002;85(7):800-7. Link.
- 27. Chotigeat U, Khorana M, Kanjanapattanakul W. Inhaled nitric oxide in newborns with severe hypoxic respiratory failure. *J Med Assoc Thailand*. 2007;90(2):266-271. Link.
- 28. Goh AY, Lum LC, Roziah M. Low-dose inhaled nitric oxide in term and near-term infants with hypoxic respiratory failure: A malaysian experience. *Med J Malaysia*. 2001;56(3):336-40. Link.
- 29. Gonzalez A, Fabres J, D'Apremont I, et al. Randomized controlled trial of early compared with delayed use of inhaled nitric oxide in newborns with a moderate respiratory failure and pulmonary hypertension. *Journal of Perinatology*. 2010;30(6):420-4. <u>Link</u>.
- Gonzalez AJ, Fabres JG, D'Apremont Ivonne, et al. Randomized trial of early use of inhaled nitric oxide in newborn with acute lung disease and pulmonary hypertension. *Pediatr* Res.1999;45(4):303A.
- 31. Ichiba H, Matsunami S, Itoh F, Ueda T, Ohsasa Y, Yamano T. Three-year follow up of term and near-term infants treated with inhaled nitric oxide. *Pediatrics International*. 2003;45(3):290-3. <u>Link</u>.
- 32. Ng SCY, Koh PL, Kao PT, Niduvaje K. Use of inhaled nitric oxide and high frequency oscillatory ventilation in refractory persistent pulmonary hypertension of the newborn secondary to meconium aspiration syndrome. *Singapore Paediatr J.* 2002;44(2):62-65.



- 33. Raimondi F, Migliaro F, Capasso L, et al. Intravenous magnesium sulphate vs. inhaled nitric oxide for moderate, persistent pulmonary hypertension of the newborn. A multicentre, retrospective study. *J Trop Pediatr*. 2008;54(3):196-9. Link.
- 34. Rhine WD, Suzuki S, Potenziano JL, Escalante S, Togari H. Efficacy of inhaled nitric oxide in neonates with hypoxic respiratory failure and pulmonary hypertension: an analysis of time to improvement in oxygenation in Japanese pediatric patients [ICCN abstract A022]. *Am J Perinatol.* 2018;35(suppl 1):A022.
- 35. Rhine WD, Suzuki S, Potenziano JL, Escalante S, Togari H. Efficacy of inhaled nitric oxide in neonates with hypoxic respiratory failure and pulmonary hypertension: an analysis of time to improvement in oxygenation in Japanese pediatric patients (Board 690) [PAS abstract 3879.690]. Abstract presented at the Pediatric Academic Societies Meeting, May 5-8 2018, Toronto, Cananda. 2018.
- 36. Sehgal A, Callander I, Stack J, Momsen T, Sterling-Levis K. Experience with inhaled nitric oxide therapy in hypoxic respiratory failure of the newborn. *Indian J Chest Dis Allied Sci.* 2005;47(4):245-249. Link.
- 37. Suzuki S, Togari H, Potenziano JL, Schreiber MD. Efficacy of inhaled nitric oxide in neonates with hypoxic respiratory failure and pulmonary hypertension: the Japanese experience. *J Perinat Med*. 2018;46(6):657-663.
- 38. Wang Yi-fei, Liu Cui-qing, Gao Xi-rong, et al. Effects of inhaled nitric oxide in neonatal hypoxemic respiratory failure from a multicenter controlled trial. *Chin Med J (Engl)*. 2011;124(8):1156-1163. Link.
- 39. Yamaguchi N, Togari H, Takase M, et al. A prospective clinical study on inhaled nitric oxide therapy for neonates in Japan. *Pediatrics International*. 2001;43(1):20-5. <u>Link</u>.

#### **Cost Effectiveness Studies**

- 40. Angus DC, Clermont G, Watson RS, Linde-Zwirble WT, Clark RH, Roberts MS. Cost-effectiveness of inhaled nitric oxide in the treatment of neonatal respiratory failure in the United States. *Pediatrics*. 2003;112(6):1351-1360. <u>Link</u>.
- 41. Armstrong EP, Dhanda R. Cost-effectiveness of early compared to late inhaled nitric oxide therapy in near-term infants. *Curr Med Res Opin.* 2010;26(12):2795-800. <u>Link</u>.
- 42. Lonnqvist PA. Efficacy and economy of inhaled nitric oxide in neonates accepted for extracorporeal membrane oxygenation. *Acta Physiol Scand*. 1999;167(2):175-9. Link.
- 43. Lorch SA, Cnaan A, Barnhart K. Cost-effectiveness of inhaled nitric oxide for the management of persistent pulmonary hypertension of the newborn. *Pediatrics*. 2004;114(2):417-26. <u>Link</u>.

### **Neurodevelopmental Follow-up Studies**

- 44. Finer NN, Vohr BR, Robertson CM, Verter J, Wright LL, Ehrenkranz RA. Inhaled nitric oxide and hypoxic respiratory failure in term infants: Neurodevelopmental follow-up [APS/SPR abstract 1150]. *Pediatr Res.* 1999;45(4 part 2):196A.
- 45. George TN, Lindgren SD, Noble LD, Bates JN, Klein JM. Five-year neurodevelopmental outcome of infants with persistent pulmonary hypertension of the newborn treated with inhaled nitric oxide [AFMR abstract 11]. *J Investig Med.* 2000;48(5):234A.
- 46. George TN, Lindgren SD, Noble LD, Bates JN, Klein JM. Five year neurodevelopmental outcome of infants with persistent pulmonary hypertension of the newborn (PPHN) treated with inhaled nitric oxide (iNO) [PAS/AAP abstract 1831]. *Pediatr Res.* 2000;47(4 part 2):310A.
- 47. Konduri GG, Vohr B, Robertson C, et al. Early inhaled nitric oxide therapy for term and near-term newborn infants with hypoxic respiratory failure: Neurodevelopmental follow-up. *J Pediatr*. 2007;150(3):235-40, 240.e1. Link.

There is a vast body of clinical data in the peer-reviewed literature regarding the therapeutic use of inhaled nitric oxide. For more information, please contact our Medical Information Group by phone at 800.844.2830, by fax at 913.451.6409, or by email at medinfo@mnk.com