VELETRI® (epoprostenol)
VELETRI - Coronavirus Disease 2019 (COVID-19)

SUMMARY

- A multicenter retrospective study at a large academic institution was conducted to evaluate mechanically ventilated patients with confirmed SARS-CoV-2 infection who were treated with inhaled nitric oxide (iNO) or inhaled epoprostenol (iEPO) during hospitalization. There were no significant differences in the mean PaO2/FiO2 (P/F) ratio at baseline and at 1 hour. No safety data was reported.[1]
- No randomized clinical trials evaluating the use of VELETRI for injection with coronavirus (COVID-19) have been published.
- The decision to use VELETRI for injection as an inhaled therapy for patients with acute respiratory distress syndrome (ARDS) may be made by the treating physician, at their sole responsibility, to treat a life-threatening condition in an intensive care setting.
- For patients currently using VELETRI for injection who have been diagnosed with coronavirus (COVID-19), clinicians should use clinical judgment to decide whether to delay treatment until the patient is recovered or continue treatment as scheduled. It will be important to evaluate the risk-benefit of continued treatment based on the patient's clinical status in terms of PAH symptoms versus the severity of symptoms from coronavirus (COVID-19).
- If a decision is made to continue treatment, appropriate precautions should be taken to minimize the potential for spread of infection and to protect clinical staff.
- Additional studies on inhaled epoprostenol are listed below in REFERENCES for review.[2-4]
- Additional abstracts on inhaled epoprostenol are listed below in REFERENCES for review.[5-12]

CLINICAL DATA

Inhaled Epoprostenol

Poonam et al (2022)[1] conducted a multicenter retrospective study at a large academic institution to evaluate mechanically ventilated patients with confirmed SARS-CoV-2 infection who were treated with iNO or iEPO during hospitalization between March 1, 2020 and June 30, 2020. Patients were excluded if they received a combination of both treatments. The primary outcome was the change in P/F ratio after 1 hour of vasodilator therapy; positive response was defined as a ≥20% increase in partial pressure of oxygen (PaO2).

A total of 103 patients were included in the analysis (iEPO, n=62; NO, n=41). At baseline, the mean (standard deviation [SD]) age was 62.9 (10.5) and 57.2 (12.6) years in the iEPO and iNO groups, respectively, and the mean weight (SD) was 87.6 (20.1) kg and 105 (43.8) kg in the iEPO and iNO groups, respectively. There were no patients with PAH at baseline in the iEPO group and 2 (4.9%) patients had PAH at baseline in the iNO group. The median (interquartile range [IQR]) total days of treatment was 4 (2-5 days) in the iEPO group and 4 (2-6) days in the iNO group. The mean (SD) P/F ratio at baseline were 85.1 (28.3) in the iEPO group and 96.8 (124) in the iNO group (p=0.556). At 1 hour, the mean (SD) P/F ratio were 107 (57.6) in the iEPO group and 116 (70.3) in the iNO group (p=0.499). There were no significant differences in either timeframe. No safety data was reported.

ADDITIONAL INFORMATION AND RESOURCES

Please note, this is not a complete list of **publicly available** resources available pertaining to this topic.

Publicly Available Websites: U.S. Government and World Health Organization

- For information from the U.S. Centers for Disease Control and Prevention (CDC), visit: Coronavirus Disease 2019 (COVID-19).

- For information from the U.S. Food and Drug Administration (FDA), visit: Coronavirus Disease 2019 (COVID-19).
- For information from the World Health Organization (WHO), visit: Coronavirus disease (COVID-19) outbreak.

Publicly Available Websites: Patient-Related Foundations within the Janssen Pulmonary Hypertension Therapeutic Area

- American Lung Association (ALA): Protecting Yourself During the Spread of the Coronavirus or COVID-19
- Pulmonary Hypertension Association (PHA): A Message from PHA's Scientific Leadership Council Chair on COVID-19

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 21 January 2025.

REFERENCES

1. Poonam PBH, Koscik R, Nguyen T, et al. Nitric oxide versus epoprostenol for refractory hypoxemia in Covid-19. *PLoS One*. 2022;17(6):e0270646.

2. Kataria V, Ryman K, Tsai-Nguyen G, et al. Evaluation of aerosolized epoprostenol for hypoxemia in non-intubated patients with coronavirus disease 2019. *Hosp Pract (1995)*. 2022;50(2):118-123.

3. Lubinsky AS, Brosnahan SB, Lehr A, et al. Inhaled pulmonary vasodilators are not associated with improved gas exchange in mechanically ventilated patients with COVID-19: a retrospective cohort study. *J Crit Care*. 2022;69:153990.

4. Chiles JW, Vijaykumar K, Darby A, et al. Use of inhaled epoprostenol with high flow nasal oxygen in non-intubated patients with severe COVID-19. *J Crit Care*. 2022;69:153989.

5. Ochogbu O, Delgado C, Carrillo M, et al. Comparing outcomes in responders versus nonresponders to inhaled epoprostenol in COVID-19 ARDS. presented at: 52nd Society of Critical Care Medicine Critical Care Congress; 44949; San Francisco, CA.

6. Khurana N, Thompson A, Duong H, et al. High-flow nasal canula and inhaled epoprostenol response in COVID-19. presented at: CHEST Annual Meeting; 45221; Nashville, TN.

7. Pino M, Bessette K, Sharofi S, et al. Utilizing combination therapy with inhaled epoprostenol and loop diuretics in acute hypoxic respiratory failure from COVID-19. presented at: CHEST Annual Meeting; 45221; Nashville, TN.

8. Strauser B, Wodtke J. Assessment of the duration of inhaled epoprostenol therapy for the treatment of ARDS due to COVID-19 and associated mortality. presented at: ACCP Virtual Symposium; 45129; Virtual.

9. Hon S, HonShideler C, Simmons-Beck R, et al. Inhaled epoprostenol effects on SpO2/FiO2 ratios and survival in COVID-19 and non-COVID-19 ARDS. presented at: International Conference of the American Thoracic Society; 45068; San Francisco, CA.

10. Jaber J, Austin A, Reddy R, et al. Inhaled epoprostenol use in SARS-CoV2 related severe hypoxic respiratory failure to prevent mechanical ventilation. presented at: International Conference of the American Thoracic Society; 45068; San Francisco, CA.

11. Diep U, Tran N, Ferguson K, et al. Evaluation of outcomes with inhaled epoprostenol in nonintubated ICU patients with COVID-19. Abstract presented at: 51st Society of Critical Care Medicine Critical Care Congress; January 2022; San Juan, PR.

12. Davis H, Mitchell C, Moore C, et al. Improved oxygenation and outcomes with inhaled Epoprostenol in ARDS secondary to covid-19. Abstract presented at: 2024 Critical Care Congress; January 21-23, 2024; Phoenix, AZ.