PRESS RELEASE
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SEDANA MEDICAL COMMENTS ON PUBLICATION OF INVESTIGATOR INITIATED STUDY RESULTS (SESAR)

Sedana Medical AB (publ) today issues a statement following the publication of the Investigator Initiated Study (IIS) "Sevoflurane for sedation in Acute Respiratory Distress Syndrome (ARDS)", the SESAR study, in The Journal of American Medicine (JAMA)1.

The IIS, a multicenter randomized controlled study in 37 ICUs in France, was led by professor Matthieu Jabaudon from Clermont Ferrand, France. The study was based on a smaller pilot study indicating benefits of sevoflurane in patients with ARDS. In the study, 687 patients with moderate or severe acute respiratory distress syndrome (ARDS), defined as a PaO2/FiO2 ratio below 150, were randomized to initially deep sedation with either sevoflurane via the Sedaconda ACD or intravenous propofol. Treatment duration was up to 7 days.

The primary endpoint, ventilator-free days through day 28 was lower in the sevoflurane group (median 0.0 days [IQR 0.0 to 11.9], compared with the control group median 0.0 [IQR 0.0 to 18.7]; standardized hazard ratio 0.76 [95% CI 0.5 to 0.97]). The authors of the SESAR publication conclude that these findings do not support the use of sevoflurane for sedation in critically ill patients with moderate to severe ARDS.2

Sedana Medical was not involved in the conduct of the study, except for supply of its medical device Sedaconda ACD. The study drug in SESAR - sevoflurane - is a different inhaled anaesthetic than Sedana Medical's Sedaconda (isoflurane), which is the only approved drug for ICU sedation. Sevoflurane has a different metabolism and toxicity profile compared to Sedaconda (isoflurane).3

Sedana Medical's own clinical trial SED-001, which was published in Lancet Respiratory Medicine, demonstrated that Sedaconda (isoflurane) administered via Sedaconda ACD, compared with intravenous propofol, reduces the need of opioids, facilitates spontaneous breathing, which improves lung function during and after ventilator treatment, and enables a faster and more predictable awakening.4 A subsequent posthoc analysis published in the Journal of Critical Care showed 3.5 more ICU-free days and less additional sedative use for mechanically ventilated intensive care unit (ICU) patients treated with isoflurane as the main sedative in comparison to patients receiving propofol as the main sedative.5

Peter Sackey, CMO of Sedana Medical stated "Isoflurane is currently the only approved inhaled sedative for mechanically ventilated ICU patients, and is now also approved for ICU sedation for children from the age of 3 years. Based on our own clinical trials data and safety signal detection for isoflurane sedation in European post-marketing surveillance, we are reassured by the extensive safety data for isoflurane since 40 years in anaesthesia and the last three years for ICU sedation, including its use in ARDS patients."

References:
1. Jabaudon MJ et al. Inhaled sedation in Acute Respiratory Distress Syndrome. The SESAR Randomised Clinical trial. JAMA 2025, doi: 10.1001/jama.2025.3169
2. Balasubramanian V et al, JAMA 2025, doi:10.1001/jama.2025.3023
3. Sneyd R. Avoiding kidney damage in ICU sedation with sevoflurane: use isoflurane instead. British Journal of Anaesthesia 2022
4. Meiser, A., et al (2021). Inhaled Isoflurane via the Anaesthetic Conserving Device versus Propofol for Sedation of Invasively Ventilated Patients in Intensive Care Units in Germany and Slovenia: an open-label, Phase 3, Randomised controlled, non-inferiority Trial. The Lancet Respiratory Medicine, 9(11), pp.1231–1240. doi: https://doi.org/10.1016/s2213- 2600(21)00323-4.
5. Bracht, H., et al (2023). ICU- and ventilator-free Days with Isoflurane or Propofol as a Primary Sedative – a Post-hoc Analysis of a Randomized Controlled Trial. Journal of Critical Care, [online] 78, p.154350. doi: https://doi.org/10.1016/j.jcrc.2023.154350

For additional information, please contact:

Johannes Doll, CEO, +46 (0)76 303 66 66
Johan Spetz, CFO, +46 (0)730 36 37 89
ir@sedanamedical.com

About Sedana Medical

Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve the patient's life during and beyond sedation. Through the combined strengths of the medical device Sedaconda ACD and the pharmaceutical Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated patients in intensive care.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordics, and Spain. In other parts of Europe as well as in Asia, Australia, Canada, and South- and Central America, the company works with external distributors.

Sedana Medical was founded in 2005, is listed on Nasdaq Stockholm (SEDANA) and headquartered in Stockholm, Sweden.

Attachments

Sedana Medical comments on publication of Investigator Initiated Study results (SESAR)