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Background:

Rotavirus is among the most common vaccine preventable illness in children under 5 years old. Despite increased severity of rotaviral illness in early infancy, most neonatal intensive care units (NICUs) do not administer rotavirus vaccination. The present project aims to evaluate the safety of in-neonatal intensive care unit administration of the monovalent live, attenuated rotavirus vaccination to preterm newborns in Sicily.

Methods:

From the first of March 2018 within the six most important NICUs of Sicily (three located in Palermo, two in Catania and one in Messina), and under the scientific coordination of the University of Palermo and of the Regional Health Department, rotavirus vaccination was administered to preterm newborns with gestational age ≥ 28 weeks. Vaccine administrations were performed both under hospital and outpatient settings, from 6 weeks of age and in accordance with the Sicilian Vaccination Schedule.

Results:

At the end of December 2019, 449 preterm newborns were fully vaccinated (two dose completion) against rotavirus in the six Sicilian NICUs participating to the project. Average gestational age was 31.4 (SD ± 2.7) weeks. First dose of rotavirus vaccination was administered at 6.3 (SD ± 0.6) weeks. Average weight at first dose were 2.890 (SD ± 0.456) grams. Only 8% and 2% of vaccinated newborns reported abdominal colic and fever $>38.5^{\circ}\text{C}$ in the 15 days after first dose, respectively. No one expected adverse event was observed in the 30 days after vaccination.

Conclusions:

First data obtained from this study confirms the absolute safety of monovalent rotavirus vaccination also in preterm newborns with gestational age ≥ 28 weeks. Results could represent for public health physicians and for neonatologists a key tool for standardize rotavirus vaccination in very Italian NICU.

Key messages:

- Rotavirus vaccination is extremely safe in preterm newborns with gestational age ≥ 28 weeks.
- Rotavirus vaccination should be routinely implemented in Italian and European NICUs.

Safety of in-neonatal intensive care unit administration of rotavirus vaccination among preterms

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