Servo-n HFOV Study: Safety and Performance in Neonates and Infants

NCT06114992

Status	RECRUITING
Sponsor	Maquet Critical Care AB
Enrollment	75 participants

Key Eligibility Criteria

Inclusion (7)

- Provision of written informed consent by the patient's legally designated representative(s) (may be obtained as deferred consent up to 24 hours after HFOV initiation: valid for both elective and rescue HFOV patients)
- Patients eligible for HFOV ventilation with Servo-n:
- Patient is either switched from conventional mechanical ventilation or HFOV with other device to Servo-n HFOV based on clinicians judgement (rescue HFOV). Note: the reason for the switch has to be that the patient failed to oxygenate or ventilate adequately with CMV or the other HFOV device
- ; OR
- Patient was prior without or with any type of non-invasive respiratory support and is put on invasive HFOV treatment based on clinicians judgement (elective HFOV)

... and 2 more (see full listing online)

Exclusion (7)

- Diagnosis of congenital diaphragmatic hernia
- Severe cardiac anomaly expected to need corrective surgery or catheter-based intervention within 30 days from birth
- Cyanotic heart disease
- Intracranial hemorrhage, Grade III or IV
- Congenital malformations with the exception of isolated lung hypoplasia

... and 2 more (see full listing online)

Locations (4 total)

CHU Montpellier-Arnaud de Villeneuve, Montpellier, France
Antoine-Béclère Hospital, Paris, France
Poznan University of Medical Sciences, Poznan, Poland
... and 1 more locations