

Project: POPART Trial

Project : Objectives	Design & Phase	Countries		Investigational Medical Product (IMP)	Follow-up End points	Start Date	End Date	Outcome measures
POPART study - To determine whether, among infants born before 29 Weeks of gestation, does, oropharyngeal surfactant at birth compared to no intervention reduce the rate of endotracheal intubation for respiratory failure within 120 hours of birth	Phase 3 Randomized, parallel group, controlled trial	Institution	50% Enrolment	Curosurf (Chiesi Farmaceutici, Parma, Italy) 120mg or 240mg given by injection into the oropharynx	Infants will be followed up until discharge from hospital	01/06/2017	31/05/2019	- Incidence of endotracheal intubation for respiratory failure within 120 hours of birth.
		National Maternity Hospital, Dublin, Ireland						
		Karolinska Institutet, Stockholm, Sweden	62					
		Rigshospitalet, Copenhagen, Denmark	50					
		Universita di Padova, Italy	35					
		Charles University, Prague, Czech Republic	40					
		CHU Liege, Belgium	20					
		SUS Stavanger, Norway	20					
		UNN, Tromsø, Norway	5					
		Braga, Portugal	20					
Inclusion Criteria		Exclusion Criteria			No. of Patients 250			
- Infants born before 29 weeks of gestation - Initiation of intensive care		- Major congenital anomalies including neural tube defects ,major structural cardiac anomalies (excluding PDA/ASD/VSD), abdominal wall defects and Congenital diaphragmatic hernia and major dysmorphic features with an abnormal karyotype e.g. T21, T13,T18 - Non-initiation of intensive care						