

The POPART Trial: Prophylactic Oropharyngeal Surfactant For Preterm Infants: A Randomised Trial

Interview to Prof. Colm O'Donnell



Colm O'Donnell is a neonatologist and a professor at the National Maternity Hospital & Our Lady's Children's Hospital; University College Dublin; Director of Clinical Research, National Children's Research Centre in Dublin, Ireland. He is a clinical researcher with particular interest in neonatal resuscitation and respiratory support of premature infants. He is a principal investigator on several randomized controlled trials (RCTs) of interventions in the delivery rooms and neonatal intensive care unit (NICU). We recently spoke to him about the use of the prophylactic oropharyngeal surfactant for preterm infants, the **POPART trial** and the importance of establishing multinational neonatal clinical trials and research infrastructures.

Being a neonatologist and often dealing with preterm babies — is it hard to work with such tiny babies born earlier than 28 weeks?

CD: It can be demanding because premature babies are **very fragile** and they need a lot of support. It is a very difficult time for families and you need to be psychologically prepared to deal with difficult situations with such tiny babies. At the same time, however, the babies are often amazingly resilient, and it is brilliant to see them surviving and thriving despite having been so vulnerable.

Also, I wish they would improve their sense of timing – they often arrive in the middle of the night at the weekend, which can be exhausting. But despite this fact, I really like it! It is a privilege to look after them. It is a very rewarding job that I very much enjoy.

How has the survival rate of preterm babies evolved in the recent years?

CD: The change has been phenomenal. In the 1970s in Ireland there was little hope of survival for a baby born at 28 weeks of gestation. Now **the survival rate across Europe is > 80%** and relatively few of the survivors have severe problems throughout their lives.

What is the POPART Trial about and what is new about this study?

CD: Many premature babies develop **breathing difficulty** after birth. Their lungs are immature and they have a relative lack of **surfactant**, a substance that is produced naturally in the lungs late in pregnancy that makes it easier for them to expand. Premature babies who have respiratory distress after birth are given breathing support with continuous positive airway pressure (**CPAP**). Babies whose breathing gets worse despite CPAP are given animal-derived surfactant directly into the lungs. About half of the premature babies who start on CPAP later receive surfactant. Animal-derived surfactant is an effective and safe treatment that has been used for **more than 20 years**. However, accessing the trachea to give it is always unpleasant and sometime dangerous for babies. Intubation is associated with long-term problems in babies and it is difficult for doctors to perform.

In the (Prophylactic Oropharyngeal surfactant for Preterm babies: A Randomised Trial) study, we are examining whether, in addition to CPAP, giving premature babies surfactant into the pharynx immediately after birth so that they will aspirate it directly into their lungs will reduce the number of them that are later intubated for breathing support.

Academic trials unlike commercial trials often face a lack of funding and adequate infrastructures. In this context, which resources does PedCRIN offer?

CD: Trials can be completed **much more quickly** and their **results are more relevant** if they are performed in many centres in different countries. To enable this to happen, an enormous number of administrative tasks must be completed. Applications need to be made to ethics committees and competent authorities in different languages in different countries. If these are successful, trials need to be conducted and monitored consistent with **Good Clinical Practice guidelines** and European legislation. Clinicians and researchers have neither the knowledge nor the skills to perform these tasks. This is where PedCRIN comes into the picture. Without their assistance with these procedures, performing multinational trials is impossible.

How difficult is it to recruit families that will agree to participate in this kind of trial?

CD: It is easier than you might think! Despite the difficult situation families find themselves in, they understand that research benefits babies and the vast majority of parents at my hospital are happy to participate. This is largely due to the work of my colleague **Madeleine Murphy**, who is undertaking a PhD.

What is the most satisfying part of working on the neonatal clinical trials?

CD: Huge advances have been made in the care of premature infants over recent years. Many more babies survive with a good quality of life today **thanks to knowledge that has been gained from clinical trials**. The most satisfying part of working on neonatal clinical trials is continuing that important process of evolution, continuing to refine and improve our care so more babies can survive with a good quality of life.

How many people are on the team?

CD: It is a pretty small team here (*laughs*). There are two of us, Madeleine and myself. However, the trial could not work without the huge support that we receive from our nursing and medical colleagues here in Dublin. We're very grateful to them.