Protocol: Prophylactic oropharyngeal surfactant for preterm infants: a randomised trial (THE POPART TRIAL)

<table>
<tr><th>Project : Objectives</th><th>Design & Phase</th><th>Countries</th><th>Investigational Medical Product (IMP)</th><th>Follow-up End points</th><th>Start Date</th><th>End Date</th><th>Outcome measures</th></tr>
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<td>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</td>
<td>Phase 3

Randomized, parallel group, controlled trial</td>
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<table>
<tr><th>Institution</th><th>50% Enrolment</th></tr>
<tr><td>National Maternity Hospital, Dublin, Ireland</td><td></td></tr>
<tr><td>Karolinska Instituet, Stockholm, Sweden</td><td>62</td></tr>
<tr><td>Rigshospitalet, Copenhagen, Denmark</td><td>50</td></tr>
<tr><td>Universita di Padova, Italy</td><td>35</td></tr>
<tr><td>Charles University, Prague, Czech Republic</td><td>40</td></tr>
<tr><td>CHU Liege, Belgium</td><td>20</td></tr>
<tr><td>SUS Stavanger, Norway</td><td>20</td></tr>
<tr><td>UNN, Tromsø, Norway</td><td>5</td></tr>
<tr><td>Braga, Portugal</td><td>20</td></tr>
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<td>Curosurf (Chiesi Farmeceutici, Parma, Italy) 120mg
or
240mg given by injection into the oropharynx</td>
<td>Infants will be followed up until discharge from hospital</td>
<td>01/06/2017</td>
<td>31/05/2019</td>
<td>- Incidence of endotracheal intubation for respiratory failure within 120 hours of birth.</td>
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<tr><td colspan="2">Inclusion Criteria</td><td colspan="3">Exclusion Criteria</td><td colspan="3" rowspan="2">No. of Patients
250</td></tr>
<tr><td colspan="2">- Infants born before 29 weeks of gestation
- Initiation of intensive care</td><td colspan="3">- 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</td></tr>
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