

Doxapram Therapy in Preterm Infants (DOXA Trial)

NCT04430790

Status	RECRUITING
Phase	Phase 3
Sponsor	Erasmus Medical Center
Enrollment	396 participants

Key Eligibility Criteria

Inclusion (6)

- Admitted to the neonatal intensive care unit (NICU) of one of the participating centres
 - Written informed consent of both parents or legal representatives
 - Gestational age at birth < 29 weeks
 - Caffeine therapy, adequately dosed (see also under co-medication)
 - Optimal Non-invasively supported with nasal Continuous Positive Airway Pressure (CPAP) or ventilation ((S)NIPPV, NIV-NAVA, BIPAP/Duopap, SIPAP)
- ... and 1 more (see full listing online)

Exclusion (5)

- Previous use of open label doxapram
- Use of theophylline (to replace doxapram)
- Chromosomal defects (e.g. trisomy 13, 18, or 21)
- Major congenital malformations that: compromise lung function (e.g. surfactant protein deficiencies, congenital diaphragmatic hernia); result in chronic ventilation (e.g. Pierre Robin sequence); increase the risk of death or adverse neurodevelopmental outcome (congenital cerebral malformations, chromosomal abnormalities);
- Palliative care or treatment limitations because of high risk of impaired outcome.

Locations (24 total)

St Luc Louvain, Brussels, Avenue Hippocrate 10, Belgium
Delta Hospital Brussels, Brussels, Brussels Capital, Belgium
University Hospital Brussels, Jette, Brussels Capital, Belgium
... and 21 more locations