

Efficacy and Safety of Zelpultide Alfa in Preterm Neonates at High Risk of Developing Bronchopulmonary Dysplasia (BPD)

NCT06897839

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Airway Therapeutics, Inc.
Enrollment	366 participants

Key Eligibility Criteria

Inclusion (4)

- Born between gestational age (GA) 22 0/7 to 27 6/7 weeks, inclusive.
- Received at least 1 dose of SOC-indicated animal-derived pulmonary surfactant treatment after birth.
- Intubated and on invasive mechanical ventilation per SOC.
- Informed consent and personal information authorization form signed by the subject's parent(s) or legal guardian(s).

Exclusion (10)

- Birth weight \leq 400 g or \geq 1,500 g.
- Major apparent congenital abnormalities impacting cardio and pulmonary function identified before randomization, such as, but not limited to:
 - Clinically relevant Potter-like syndrome and any pulmonary congenital anomalies,
 - Clinically relevant congenital diaphragmatic hernia,
 - Omphalocele or gastroschisis, esophageal atresia,
- ... and 5 more (see full listing online)

Locations (20 total)

Bnai Zion Medical Center, Haifa, Israel
Shaare-Zedek Medical Center, Jerusalem, Israel
Ziv Medical Center, Safed, Israel
... and 17 more locations