

Study to Assess the Safety, Tolerability, and Preliminary Efficacy of ST266 in Infants With Necrotizing Enterocolitis

NCT06315738

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Noveome Biotherapeutics, formerly Stemnion
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (2)

- Infants born from e26 weeks gestational age to 40 weeks gestational age; up to 40 weeks postmenstrual gestational age (gestational age plus chronological age in terms of weeks) with current weight at diagnosis of NEC between e800g and d3000g as a result of prematurity and/or IUGR. Parent(s)/legal medical representative(s) voluntarily provides written consent prior to study enrollment.
- Minimum Bell stage IIA NEC diagnosis by radiologic confirmed pneumatosis intestinalis and may include intestinal dilation and ileus.

Exclusion (16)

- Infants with abdominal perforation at less than 10 days of life
 - Not expected to survive e2 weeks or born with a lethal condition requiring hospice or palliative care (e.g., disease has progressed to NEC totalis, or patient has multi-organ system failure).
 - Born with major congenital anomalies such as cardiac defects (e.g., Tetralogy of Fallot) or chromosomal disorders/anomalies (e.g., neural tube defect).
 - Mother's receipt of any investigational product during pregnancy.
 - Infants with malignancies (e.g., neoplastic cell growth as a solid tumor or a blood neoplasm, such as congenital leukemia).
- ... and 11 more (see full listing online)

Locations (7 total)

Yale-New Haven Hospital, New Haven, Connecticut, United States
Orlando Health, Inc. Winnie Palmer Hospital for Women and Babies, Orlando, Florida, United States
BayCare Health System-St. Joseph's Women's Hospital, Tampa, Florida, United States
... and 4 more locations