A Clinical Efficacy and Safety Study of OHB-607 in Preventing Bronchopulmonary Dysplasia in Extremely Premature Infants

Status: RECRUITING

Eligibility Criteria

Age: 0 hours to 24 hours old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Written informed consents and/or assents must be signed and dated by the participant's parent(s) prior to any study related procedures. The informed consent and any assents for underage parents must be approved by the IRB/IEC (in accordance with local regulations). 2. Written informed consents and/or assents must be signed and dated by the participant's birth mother prior to providing study-related information related to birth mother medical history, pregnancy and the birth of the participant. The informed consent and any assents for underage birth mothers must be approved by the IRB/IEC (in accordance with local regulations). 3. Subjects must be between 23 weeks +0 days and 27 weeks +6 days GA, inclusive.

Exclusion Criteria:

1. Detectable major (or severe) congenital malformation identified before randomization. 2. Known or suspected chromosomal abnormality, genetic disorder, or syndrome, identified before randomization, according to the investigator's opinion. 3. Hypoglycemia at Baseline (blood glucose less than (\<) 45 milligrams per deciliter \[mg/dL\] or 2.5 milli moles per liter \[mmol/L\]) which persists in spite of glucose supplementation, to exclude severe congenital abnormalities of glucose metabolism. 4. Clinically significant neurological disease identified before randomization according to cranial ultrasound (hemorrhages confined to the germinal matrix are allowed) and investigator's opinion. 5. Any other condition or therapy that, in the investigator's opinion, may pose a risk to the participant or interfere with the participant's potential compliance with this protocol or interfere with interpretation of results. 6. Current or planned participation in a clinical study of another investigational study treatment, device, or procedure (participation in non-interventional studies is permitted on a case-by-case basis). 7. The participant or participant's parent(s) is/are unable to comply with the protocol or is unlikely to be available for long-term follow-up as determined by the investigator. 8. Birth mother with active COVID-19 infection at birth or a history of severe COVID-19 infection (requiring intensive care hospitalization) during pregnancy. 9. Birth mother with known HIV or hepatitis (B, C, or E) infection.

Conditions & Interventions

Interventions:
DRUG: OHB-607
Conditions:
Bronchopulmonary Dysplasia, Chronic Lung Disease of Prematurity, Intraventricular Hemorrhage, Retinopathy of Prematurity (ROP)

More Information

Contact(s): OHB Contact - CMO@Oakhillbio.com
Principal Investigator: Rozycki, Henry
Phase: PHASE2
IRB
Number: HM20016299
System ID: NCT03253263

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