BEATRIX: A Study to Learn About a Group B Streptococcus Vaccine in Healthy Pregnant Women and Their Babies

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 day to 49 years old
Healthy Volunteers: This study is also accepting healthy volunteers
Key Inclusion criteria- Maternal:

- Healthy pregnant women ≤49 years of age who are between 24 0/7 and 36 0/7 weeks of gestation on the day of planned vaccination, with an uncomplicated, singleton pregnancy, and who have no known increased risk of complications.
- Had a fetal anomaly ultrasound examination with no significant fetal abnormalities observed.
- Documented negative human immunodeficiency virus (HIV) antibody test, syphilis test, and hepatitis B virus (HBV) surface antigen test during this pregnancy and prior to randomization.
- Capable of giving personal signed informed consent.
- Willing to give informed consent for her infant to participate in the study.

Key Exclusion criteria- Maternal:

- Prepregnancy body mass index (BMI) of >40 kg/m2.
- Current pregnancy complications or abnormalities that may increase the risk associated with the participation in and completion of the study.
- Prior pregnancy complications or abnormalities that, based on the investigator's judgment, may increase the risk associated with the participation in and completion of the study.
- History of microbiologically proven invasive disease caused by GBS in the current pregnancy.
- A known or suspected infection during the current pregnancy that may increase the risk of complications in pregnancy (eg, active tuberculosis, syphilis, primary genital herpes simplex, malaria).

Key Inclusion criteria- Infant Participants

- Evidence of a signed and dated ICD signed by the parent(s)/legally authorized representative or legal guardian

Key Exclusion Criteria - Infant Participants:

- Children or grandchildren who are direct descendants of investigator site staff or sponsor and sponsor delegate employees directly involved in the conduct of the study.

Key Exclusion Criteria - Infant immunogenicity subset Participants:

- Children with a known or suspected contraindication to any vaccine administered in the infant vaccine immunogenicity subset.

Refer to the study contact for further eligibility details

Conditions & Interventions

Interventions:
BIOLOGICAL: Multivalent Group B streptococcus vaccine, BIOLOGICAL: Placebo, BIOLOGICAL: Infanrix hexa, BIOLOGICAL: Prevenar 20, BIOLOGICAL: Pediarix, BIOLOGICAL: Prevnar 20, BIOLOGICAL: Infanrix
Conditions:
Healthy
Keywords:
group B streptococcus, maternal immunization, vaccine

More Information

Description:
BEATRIX (group B strEptococcus mATeRnal and Infant VaX study) The purpose of this study is to learn about the safety and how the group B streptococcus (GBS) vaccine works in pregnant women and their babies. This study is seeking healthy pregnant participants: * aged 49 or younger who can join. * between 24 and 36 weeks of gestation ("Gestational age" is a medical term used to describe how far along your pregnancy is) * had a fetal ultrasound examination performed with no major fetal abnormalities observed * documented negative for HIV, syphilis and Hepatitis B All participants in this study will receive only 1 shot in an arm. This could either be a group B streptococcus 6-valent polysaccharide conjugate vaccine (GBS6) or placebo. Placebo is an inactive substance used in the study for comparison purposes; in this study, the placebo injection will be saline (saltwater). The pregnant participants may take part in this study for a maximum of 14 months (6 months after delivery) , and their babies for about 12 months after they are born. The pregnant participants will need to visit the research site at least 3 to 4 times with some visits permitted to occur over the telephone. A subset of infants will be asked to take part in the study for up to 19 months. The subset will receive diphtheria toxoid-containing vaccine and/or pneumococcal vaccine following each country's standard immunization plan and have blood drawn 1 month after completion of the primary and/or toddler (booster) doses.

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Principal Investigator ID:
Phase: PHASE3
IRB Number:
System ID: NCT07160244
