A Phase 3 Study of Revaccination in Subsequent Pregnancies With Bivalent RSV Vaccine and Duration of Protection of a Single Dose

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: Not specified
Healthy Volunteers: This study is also accepting healthy volunteers
Pregnant Participants-Cohort 1 and Cohort 2 Key Inclusion Criteria

- Women aged 18 to 49 who are pregnant, between 24 and 36 weeks along, and expecting one baby without known risks for complications can participate.
- Had the RSVpreF or Abrysvo vaccine during a previous pregnancy.
- Had an ultrasound scan at 18 weeks or later during their current pregnancy, with no major fetal problems detected.
- Based on their medical history, physical check-up, and the doctor's judgment, they are found suitable to join the study.
- Agrees to let their baby take part in the study and gives their permission.
- Able to sign a consent form, agreeing to follow the rules and conditions of the study.

Key Exclusion Criteria

- Received any approved or experimental RSV vaccine since their previous pregnancy.
- Has a pre-pregnancy body mass index (BMI) over 40 kg/m2.
- History of a severe bad reaction to a vaccine or a serious allergic reaction (like anaphylaxis) to any ingredient in the study vaccine or a similar vaccine.
- Current pregnancy problems or issues at the time of giving consent.
- Previous pregnancy issues or problems at the time of giving consent.
- Women who are breastfeeding at the time of enrollment

Infant Participants

- Proof that the parent(s) or legal guardian(s) has signed and dated a consent form.
- Parent(s) or legal guardian(s) must agree to attend scheduled visits and follow the study plan, including laboratory tests and other procedures.

Nonpregnant Participants-Cohort 3 Key Inclusion Criteria

- Have already received one dose of the RSVpreF vaccine during their previous pregnancy as part of the Pfizer clinical trial, and the results from that time can be used for this study.
- Able to sign a consent form, agreeing to follow the rules and requirements of the study.

Key Exclusion Criteria

- Received any approved or experimental RSV vaccine after participating in the Pfizer clinical trial.
- Taking part in other studies with new drugs within 28 days before giving consent or during the study period.

Conditions & Interventions

Interventions:
BIOLOGICAL: RSVpreF, BIOLOGICAL: Placebo
Conditions:
RSV Infection
Keywords:
Pregnancy, RSV vaccine, RSV, Maternal immunization

More Information

Description:
This study aims to check how safe and well-tolerated a second dose of RSVpreF is when given during later pregnancies, and to see how long the immunity lasts from a single dose given during a previous pregnancy by examining the blood of nonpregnant participants who had the vaccine before.

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Phase: PHASE3
IRB Number:
System ID: NCT06866405

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