

A Follow-up Trial of GBS-NN/NN2 Vaccine in Healthy Pregnant Women

NCT06592586

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Minervax ApS
Enrollment	338 participants

Key Eligibility Criteria

Inclusion (5)

- Participant living in Denmark or South Africa who has participated either in Trial MVX0004 (NCT05154578) or MVX0005 (NCT04596878) and has received at least 1 dose of the GBS-NN/NN2 vaccine.
- Participant who is able to read and understand and capable of giving personal signed informed consent.
- Participant who is willing and able to comply with scheduled visits, the investigational plan, and other trial procedures.
- Participant who is granting access to their trial-related medical records and to their trial materials from Trials MVX0004 or MVX0005, whatever is applicable.
- Participant who are expected to be available for the duration of the trial and who can be contacted by telephone during trial participation.

Exclusion (9)

- Any personnel involved in the conduct of the trial (and their family members), including, but not limited to, site staff members, MinervaX employees, and any vendor or contract research organisation (CRO) employees.
 - Participant with confirmed Group B Streptococcus (GBS) infection since participation in Trial MVX0004 or MVX0005.
 - Participant with any psychiatric condition, including recent (within the past year) active suicidal ideation/behaviour that may increase the risk of trial participation or, in the investigator's judgement, make the participant unsuitable for participation in the trial.
 - Participant who participated in other trials involving investigational drug(s) or devices within 28 days prior to trial entry, and/or are participating in other trials involving investigational drug(s) or devices at trial entry, or plan to (continue to) participate in other trials involving investigational drug(s) or devices during this trial.
 - Participant with known or suspected immunodeficiency or cancer or a family history of congenital or hereditary immunodeficiency.
- ... and 4 more (see full listing online)

Locations (6 total)

Hvidovre Hospital - Department Of Obstetrics And Gynaecology, Copenhagen, Capital Region, Denmark
Aarhus Universitetshospital, Aarhus N, Central Jutland, Denmark
Sygehus Lillebælt - Kolding Sygehus, Kolding, Region Syddanmark, Denmark
... and 3 more locations