A Worldwide Pregnancy Safety Study to Assess Maternal, Fetal, and Infant Outcomes Following Exposure to Efgartigimod During Pregnancy and/or Breastfeeding.

NCT06299748

Status	RECRUITING
Sponsor	argenx
Enrollment	279 participants

Key Eligibility Criteria

Inclusion (2)

- Women with exposure to efgartigimod or efgartigimod PH20 SC any time within 25 days prior to conception or any time during pregnancy, or women with exposure to efgartigimod or efgartigimod PH20 SC during breastfeeding. The timeframe of 25 days prior to conception is calculated based on five times the efgartigimod half-life, which is 3 to 5 days.
- Written/verbal informed consent or eConsent (depending on country regulations) (for adolescents under the age of majority, written/verbal informed assent or eConsent by the pregnant minor (where applicable) and written/verbal informed consent or eConsent by the parent/legal guardian).

Exclusion (1)

- None

Locations (4 total)

United BioSource LLC, Morgantown, West Virginia, United States
Klinikum der Ruhr-Universität Bochum St. Josef Hospital Neurologische Interdisziplinäre Infusionsambulanz + MS Studienambulanz (Haus E Ebene1), Bochum, Germany
Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma, Italy
... and 1 more locations