ForPatients
by Roche

Multiple Sclerosis (MS)Clinically Isolated Syndrome (CIS)

A Study Evaluating B Cell Levels In Infants Potentially Exposed To Ocrelizumab During Pregnancy

Trial Status	Trial Runs In	Trial Identifier
Completed	5 Countries	NCT04998812 2021-000062-14 2024-510974-25-00 MN42988

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase IV Multicenter, Open-Label Study Evaluating B Cell Levels In Infants Potentially Exposed To Ocrelizumab During Pregnancy

Trial Summary:

This study will evaluate the potential placental transfer of ocrelizumab in pregnant women with clinically isolated syndrome (CIS) or multiple sclerosis (MS) [in line with the locally approved indications] whose last dose of ocrelizumab was administered any time from 6 months before the last menstrual period (LMP) through to the first trimester (up to gestational week 13) of pregnancy, and the corresponding pharmacodynamic effects (B cell levels) in the infant.

Hoffmann-La Roche	Phase 4
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	#18 Years & # 40 Years	No

Inclusion Criteria:

- Diagnosis of MS or CIS (in line with the locally approved indications)
- Currently pregnant with singleton pregnancy at gestational week #30 at enrolment

- Documentation that first and second obstetric ultrasound has been conducted before enrolment during the screening period
- Documentation that the last exposure to ocrelizumab occurred up to 6 months before the LMP before the woman became pregnant OR during the first trimester of pregnancy

Exclusion Criteria:

- Last exposure to ocrelizumab >6 months before the woman's LMP or later than the first trimester of pregnancy
- Gestational age at enrolment >30 weeks
- Non-singleton pregnancy
- Received the last dose of ocrelizumab at a different posology other than per the local prescribing information
- Lack of access to ultrasound pre-natal care as part of standard clinical practice
- Prior or current obstetric/gynecological conditions associated with adverse pregnancy outcomes
- Pre-pregnancy body mass index >35 kg/m2
- Any concomitant disease that may require chronic treatment with systemic corticosteroids or immunosuppressants during the course of the study
- Prior or current history of primary or secondary immunodeficiency, or woman in an otherwise severely immunocompromised state
- Significant and uncontrolled disease that may preclude a woman from participating in the study
- Women with known active malignancies or being actively monitored for recurrence of malignancy including solid tumors and hematological malignancies
- Prior or current history of alcohol or drug abuse, or current use of tobacco
- Positive screening tests for hepatitis B
- Treatment with drugs known to have teratogenic effects
- Planned treatment with interferons, glatiramer acetate, or pulsed corticosteroids as a bridging therapy after the last ocrelizumab dose and throughout pregnancy
- Treatment with disease-modifying therapies for MS within their respective half-lives prior to the last ocrelizumab dose or prior to the LMP
- Treatment with natalizumab within 12 weeks prior to the LMP
- Treatment with teriflunomide within the last two years, unless measured plasma concentrations are <0.02 mg/L. If levels are >0.02 mg/L or not known, an accelerated elimination procedure is required
- Treatment with any investigational agent within 6 months or five half-lives of the investigational drug prior to the last ocrelizumab dose or prior to the LMP