ForPatients
by Roche

Multiple Sclerosis (MS)Clinically Isolated Syndrome (CIS)

A Study Evaluating B Cell Levels In Infants Of Lactating Women With CIS Or MS Receiving Ocrelizumab

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT04998851 2021-000063-79 MN42989

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 Of Lactating Women With CIS Or MS Receiving Ocrelizumab

Trial Summary:

This study will evaluate the pharmacokinetics of ocrelizumab in the breastmilk of lactating women with clinically isolated syndrome (CIS) or multiple sclerosis (MS) [in line with the locally approved indications] treated with ocrelizumab, by assessing the concentration of ocrelizumab in mature breastmilk, as well as the corresponding exposure and pharmacodynamic effects (blood B cell levels) in the infants.

Hoffmann-La Roche
Sponsor

Phase 4
Phase

NCT04998851 2021-000063-79 MN42989
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Woman is between 18 and 40 years of age at screening
- Woman is willing to breastfeed for at least 60 days after the first post-partum ocrelizumab infusion (this decision is to be taken prior to and independent from study participation)
- Woman is willing to provide breastmilk samples

- Woman has a diagnosis of MS or CIS (in line with the locally approved indications)
- Woman has delivered a healthy term singleton infant (#37 weeks gestation)
- Infant is between 2-24 weeks of age at the time of the mother's first post-partum dose of ocrelizumab
- For women who received commercial ocrelizumab (OCREVUS) before enrolment: documentation that last exposure to ocrelizumab occurred more than 3 months before the last menstrual period (LMP) and was given at the approved dose of 2 x 300 mg or 1 x 600 mg
- Woman agrees to use acceptable contraceptive methods during the study

Exclusion Criteria:

Exclusion Criteria related to the Mother:

- Hypersensitivity to ocrelizumab or to any of its excipients
- Received last dose of ocrelizumab <3 months before the LMP or during pregnancy
- Active infections (may be included once the infection is treated and is resolved; women with bilateral mastitis infection should not have samples collected until the infection is completely resolved)
- Prior or current history of primary or secondary immunodeficiency, or woman in an otherwise severely immunocompromised state
- Known active malignancies, or being actively monitored for recurrence of malignancy
- History of breast implants, breast augmentation, breast reduction surgery or mastectomy
- Prior or current history of chronic alcohol abuse or drug abuse
- Positive screening tests for hepatitis B
- Treatment with a DMT for CIS or MS during pregnancy and/or first weeks post-partum, with the exception of formulations of interferon-beta, glatiramer acetate or pulsed corticosteroids
- Treatment with drugs known to transfer to the breastmilk and with established or potential deleterious effects for the infant
- Treatment with any investigational agent within 6 months or five half-lives of the investigational drug prior to the LMP

Exclusion Criteria related to the Infant:

- >24 weeks of life at the time of the mother's first dose of ocrelizumab
- Any abnormality that may interfere with breastfeeding or milk absorption
- Active infection (may be included once the infection resolves)
- Infant has any other medical condition or abnormality that, in the opinion of the investigator, could compromise the infant's ability to participate in this study, including interference with the interpretation of study results
- At least one documented brief resolved unexplained event (BRUE), as defined by the 2016 Guidelines of the American Academy of Pediatrics