Concentration of Ofatumumab in the Breast Milk of Lactating Women With Relapsing Forms of Multiple Sclerosis

Last Update: May 11, 2025

A Phase IV, Prospective, Multicenter, Open-label, Mother-milk Study to Evaluate Ofatumumab Concentration in the Breast Milk of Lactating Women With Relapsing Forms of Multiple Sclerosis Receiving Ofatumumab

ClinicalTrials.gov Identifier:
NCT06444113

Novartis Reference Number:COMB157G2410

See if you Pre-qualify

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This study will evaluate whether ofatumumab is excreted at quantifiable levels and at which concentrations in breast milk of lactating women with RMS). The study will include lactating mothers who plan to breastfeed and initiate/re-initiate ofatumumab 2-24 weeks post-partum. This is a Phase IV study in which breastfeeding mothers treated with ofatumumab and their babies are taking part for up to 1 year. The study consists of a Core Part and a Safety Follow-up Part. The Core Part includes a Screening period and a Sampling period. During the Screening period (up to 4 weeks), the study doctor will assess if mothers can join the study. The Sampling period, during which milk samples and a blood sample will be collected, will last for up to 12 weeks. The Safety Follow-up Part will last for about 9 months, to follow up on health and safety of mothers and their babies.

Condition
Multiple Sclerosis
Phase
Phase4
Overall Status
Recruiting
Number of Participants
20
Start Date
Nov 25, 2024
Completion Date
Feb 23, 2027
Gender
Female
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Ofatunumab

No study-treatment is provided for this study. Study participants will be treated with commercially available ofatumumab according to the local label.

Eligibility Criteria

Inclusion Criteria:

1. Written informed consent must be obtained before any study assessment is performed.
2. Participant is female with a relapsing form of MS and at least 18 years of age at the time of providing consent.
3. Participant must be postpartum at the time of enrollment, plan to be exclusively breastfeeding and willing to provide breast milk samples.
4. Participant has delivered term infant (at least 37 weeks gestation).
5. Participant must plan to initiate or re-initiate or have initiated or re-initiated treatment with ofatumumab between 2 to 24 weeks postpartum. The decision to be treated with ofatumumab and to breastfeed is made in accordance with the treating physician and must be completely independent of the decision to participate in this study.

Exclusion Criteria:

1. Use of any investigational drugs within 5 half-lives of enrollment, or within 30 days or until the expected pharmacodynamic effect has returned to baseline, whichever is longer.
2. Participant taking medications prohibited by the study protocol at screening.
3. Pregnant woman, confirmed by positive serum pregnancy test during screening.
4. Female of childbearing potential should use effective contraception as per local label.
5. Participant has history of chronic alcohol abuse or drug abuse in the last year.
6. Participant has any medical, obstetrical, psychiatric or other medical condition that, in the opinion of the Investigator, can jeopardize or would compromise the subject's ability to participate in this study or confound the study assessment.
7. Participant has history of breast implants, breast augmentation, or breast reduction surgery.
8. Participant has received anti-CD20 agents during the second and third trimesters of pregnancy.
9. Active infections, including mastitis (participant may be included once the infection is resolved).
10. Prior or current history of primary or secondary immunodeficiency, or participant in an otherwise severely immunocompromised state.
11. Participant with active hepatitis B disease prior to the initiation or re-initiation of ofatumumab. (Participant with positive hepatitis B serology should consult a liver disease medical standards to prevent hepatitis B reactivation.)
12. History of malignancy of any organ system (other than localized basal cell carcinoma of the skin or in situ cervical cancer), treated or untreated, within the past 5 years, regardless of whether there is evidence of local recurrence or metastases.
13. Any contraindication as per local label.
14. Participant who has an infant with any abnormality that may interfere with breastfeeding or confound the

study assessment in the opinion of the Investigator.

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