**Transcript Details**
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/neurofrontiers/the-sopranino-study-ensuring-ms-treatment-safety-for-breastfeeding-mothers/26380/

**ReachMD**
www.reachmd.com
info@reachmd.com
(866) 423-7849

---

# The SOPRANINO Study: Ensuring MS Treatment Safety for Breastfeeding Mothers

**Announcer:**
You're listening to *NeuroFrontiers* on ReachMD. On this episode, we'll discuss how ocrelizumab might affect breastfed infants of mothers with multiple sclerosis with Dr. Riley Bove. Not only is Dr. Bove a practicing neurologist and clinician scientist in the UCSF Weill Institute for Neurosciences, but she also presented a session on this exact topic at the 2024 Congress of the European Committee for Treatment and Research in Multiple Sclerosis.

Let's hear from Dr. Bove now.

**Dr. Bove:**
So this is a Phase IV study for ocrelizumab, the SOPRANINO study, and the background to the study is that MS affects 3 times more females than males and typically starts in the 20s, 30s and 40s, so during the reproductive years, so demographically, we know that females of childbearing potential are a large demographic in MS. We also know that the highest risk of relapses essentially over the disease course, when someone is diagnosed, is really in the postpartum period, so about a third of untreated females experience relapses early postpartum, and about a half have new lesions on MRI. And so we're starting to see that highly effective medications with a short onset of action, like ocrelizumab and the other B-cell-depleting medications, can really abrogate for the most part this risk of postpartum relapses if they're given early postpartum.

But what do we do for women who want to breastfeed? And so the question was what is the safety of ocrelizumab during lactation? So does it cross into the breast milk? Does it cross then to the baby? And what are the baby's ocrelizumab and B-cell levels if they're breastfeeding?

So this was really an observational study. We recruited the mothers, so they were screened in their late pregnancy and around the time of delivery, and then we included mothers who were aged 18 to 40 with a diagnosis of MS or clinically isolated syndrome. And these were people who had already decided with their clinician that they were going to breastfeed and also that they were going to start ocrelizumab while they were breastfeeding, so that was a clinical decision made by the patient and their physician, and those were the patients that we then enrolled in the study.

And what we did is we sampled both sort of maternal samples and newborn samples. We collected maternal blood and breast milk samples, and then we collected newborn blood samples as well, and we collected samples before infusion and then we collected maternal milk and blood samples before the infusion as well as after the infusions on specific days, and we collected infant blood samples 30 days after the maternal infusion.

So our first endpoint was really about ocrelizumab levels in the breast milk, and so we determined that the ocrelizumab levels in breast milk were really negligible. And so there are a couple ways of measuring that. So you approximate the baby's average daily infant dose, so ADID. You can also approximate the relative infant dose, so that's the RID. And in both cases, those levels were very, very low, so well below sort of established levels for safety, and that was really consistent with what we know about IgG. The second main outcome that we looked at was the infant serum, and so we collected blood from the infants 30 days after maternal infusion, and we found that the ocrelizumab was undetectable in nine of the nine infants, so the serum ocrelizumab concentration was below the level of quantification. So those were our two main findings.

We also looked at several other outcomes as well, such as infant B-cell levels, and all the infants had B-cell levels that were within age-specific normal ranges. And then finally, we also looked at infant safety, so infections, and mostly the infants had typical childhood

infections—so ear infections, nasopharyngitis, several had COVID—and all of the infections resolved.

And I think, finally, it's just really encouraging that we were able to do this Phase IV study. For a long time, a lot of important clinical scientific questions affecting this large MS demographic were kind of neglected, and so it's really encouraging that there's a path forward to doing this and to doing it in a rigorous and comprehensive manner.

**Announcer:**
That was Dr. Riley Bove discussing her session at the 2024 Congress of the European Committee for Treatment and Research in Multiple Sclerosis, which focused on how ocrelizumab might affect breastfed infants of mothers with multiple sclerosis. To access this and other episodes in our series, visit *NeuroFrontiers* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!