



What Breastfeeding Women Should Know About Clinical Lactation Studies

Many women need to use or receive a medical product (such as prescription medicines and vaccines) while they are breastfeeding (lactating), whether for conditions like diabetes, depression, short-term infections, or postpartum recovery. Understandably, many women worry about how the medical product they are using might affect their baby through breast milk. In some cases, this uncertainty may lead mothers to stop breastfeeding earlier than planned or to avoid using necessary medical treatment. For some medical products, studies have shown they are safe to use during breastfeeding. For others, there may be less information about whether they are safe to use while breastfeeding. As a result, breastfeeding women and their health care providers may be faced with deciding whether to continue using a medical product while breastfeeding without reliable safety data on the medical product's labeling. **This is where clinical lactation studies play an important role.**



What are clinical lactation studies?

Clinical lactation studies are research studies that collect health information about the effects medical products taken while breastfeeding may have on the breastfeeding mother and/or the breastfed baby. Some of these studies enroll healthy women who are not using the medical product. The goals of clinical lactation studies may include some or all of the following:

- Assessing the amount of medicine transferred into breast milk
- Evaluating the effect of the medicine on milk production
- Determining the risks posed by exposure to medicines through breastmilk to the baby

How clinical lactation studies work

Clinical lactation studies will typically collect information about the breastfeeding woman and the breastfed baby, track medicine intake, collect samples of breast milk and, if necessary, collect blood samples from the breastfed baby.

There are different kinds of lactation studies. For example, a milk-only study involves only samples of breast milk and is used to detect the presence and amount of the medical product in breast milk. Another type of study, known as a mother-infant pair study, requires both breast milk and blood samples from the breastfeeding woman as well as blood samples from the breastfed baby to determine the baby's absorption of the medical product through breast milk.

“FDA encourages breastfeeding women to participate in clinical lactation studies to help track the outcomes of medical products used while breastfeeding (lactating). The data collected from clinical lactation studies will be analyzed to evaluate the safety of the medical product when used while breastfeeding. The data can also be used to develop recommendations to minimize exposure of the medical product to the baby from breastmilk when appropriate.”

Why clinical lactation studies matter

- Clinical lactation studies inform health care providers about how to manage a medical product's use while a woman is breastfeeding.
- Some medical products lack clear data on their safety when used while breastfeeding. The information obtained from clinical lactation studies may help fill these gaps in knowledge and may be used to update the medical product's safety labeling.

FDA's role

In June 2015, FDA implemented a [new rule](#) on the format and content for information presented in prescription medicine and vaccine labeling. The revised “Lactation” subsection includes information about using the medical product while breastfeeding, such as whether the medical product gets into breast milk, and – based on how much of it is present – how it can possibly affect the breastfed baby.

FDA does not conduct clinical lactation studies. However, under section 505(o)(3) of FD&C Act, FDA can require a manufacturer to conduct a clinical lactation study after a medical product has been approved. Manufacturers can also volunteer to conduct clinical lactation studies.

FDA Office of Women's Health (OWH) maintains a webpage to help connect breastfeeding women and health professionals with ongoing clinical lactation studies. The webpage includes a list of studies and the contact information for breastfeeding women interested in volunteering. If you are a study sponsor and would like your clinical lactation study added to this list, please email FDA at Registries@fda.hhs.gov.

Volunteer to enroll in a clinical lactation study

If you are breastfeeding and using a medical product, you can volunteer to join a clinical lactation study if one is open and enrolling for the medical product you are receiving. If you do not find a study for the medical product you are using on the list, ask your health care provider if they can help you find a clinical lactation study. The information collected can help health care providers and others who are breastfeeding learn more about the safety of medical products used during breastfeeding. Learn more about how you can help.

This fact sheet was developed by the **FDA Office of Women's Health**. This information is for educational purposes, not all inclusive, and should not be used in place of talking with your health care provider.

For more women's health resources visit: www.fda.gov/womens.

Visit FDA Office of Women's Health Clinical Lactation Studies webpage www.fda.gov/clinicallylactationstudies for more information.

