Vedolizumab (Entyvio®) Lactation Study

A study to assess the concentration of vedolizumab (Entyvio®) in breast milk of lactating women with active ulcerative colitis or Crohn’s disease who are receiving vedolizumab therapeutically.

Study Objective:

The safety of medications to treat UC and CD during pregnancy and lactation is of significant interest to patients of childbearing potential, as many medications may be transferred in uterus or through breast milk from nursing mothers to their newborns. It has been detected in animal studies that low levels of vedolizumab were present in breast milk when vedolizumab was given at very high doses.

It is unknown whether the biologic treatment vedolizumab is present in human breast milk. The intent of this study is to what, if any, amount of vedolizumab might pass from mothers who are receiving vedolizumab therapeutically to their breast milk.

Summary:

This study has two periods and will last up to 85 days.

**Screening Period**

*Up to 4 weeks (1 visit)*

The study team checks if the study is right for the patient.

**Dosing Period/ Assessment and Collection**

*57 days (6 visits)*

On Day 1 of study, the patient will receive an intravenous infusion of vedolizumab that has been ordered as part of their treatment plan. Two breast milk collections will be performed.

Interim visits will occur at Days 4, 8, 15, and 29 either at the study center or at the patient’s home with a qualified home healthcare nurse, and breast milk will be collected.

A final visit will occur at Day 57 at the study center to collect breast milk, assess patient health, and return all study equipment.
Taking part in the study is entirely up to the patient, and she can leave the study at any time. Throughout the study, the patient will be carefully monitored by a team of doctors and nurses. All study-related healthcare procedures will be provided to the patient at no cost. In addition, reasonable travel expenses may be reimbursed.

**Eligible Patient Criteria:**

Patients may be eligible if they:

- are female and are 18 years of age or older
- were on an established vedolizumab maintenance therapy prior to the delivery of infant
- are at least 6 weeks postpartum by Day 1
- have well-established lactation and are exclusively breast feeding their infant
- plan to continue breastfeeding throughout the duration of the study

Participation in this study will not be allowed if a patient:

- is pregnant or becomes pregnant during the study
- has a history of breast implants, breast augmentation, or breast reduction surgery
- is enrolled in another clinical trial

**Site Location:**

University of Colorado Anschutz Medical Campus  
12631 East 17th Avenue  
Aurora, CO 80045

**Contact Info:**

For questions about the study or to refer a patient, please contact:

Jesse Bright  
Phone: 303-724-7875  
Email: jesse.2.bright@ucdenver.edu

More detailed information about the study can be found here