

Infant Microbiota and Probiotic Intake (IMPRINT) Study

Who is conducting this Study?

This clinical study is led by Dr. Jennifer Smilowitz, Ph.D., at the UC Davis Foods for Health Institute in collaboration with Dr. Mark Underwood, M.D., at the UC Davis Medical Center. This study has been reviewed and approved by the UC Davis Institutional Review Board.

What is the purpose of the study?

This is a clinical trial aimed at determining the effects of feeding the probiotic culture *Bifidobacterium infantis* for 21 days on fecal bacteria composition in healthy term infants. We will also determine the effect of consuming the probiotic on fecal bacteria composition 1 week and 1 month after infants no longer consume the probiotic. We will also measure the human milk oligosaccharide composition of mothers' breast milk throughout the study. All mothers will receive free private at-home lactation consultation visits and their infants will be randomly assigned into one of two groups: receive the probiotic culture or not receive the probiotic culture.

Who can participate?

- Pregnant women in their third trimester of pregnancy; OR women who have delivered their infants within the past 2 days
- Plan to exclusively breastfeed for at least 3 months
- Live in Davis, Woodland, Dixon, Vacaville or Sacramento Infants are born full term (>37 weeks gestation) and have no medical complications that would preclude breastfeeding or alter gut bacteria

Who is NOT eligible to participate?

- Mothers who do not plan to exclusively breastfeed
- Infants born with medical complications
- Mothers who experienced medical complications during labor that would prevent breastfeeding
- Infants who consume other types of probiotics
- Infants who receive antibiotics for more than the first 72 hours of life

What is expected of me during the study?

This study requires a 61 day commitment after the birth of your baby. You will be randomized into one of two groups and will either receive private lactation support OR private lactation support and be asked to feed a daily dose of *B. infantis* probiotic culture to your infant for 21 consecutive days starting when your baby is 7 days old. Either researchers or study personnel will instruct you on how to administer the culture to your baby. You will also be asked to collect 5 breast milk samples, 2 stool samples from you and 10 stool samples from your baby's diaper. The Clinical Coordinator and Lactation Consultant will instruct you on how to collect and store samples in your freezer until a scheduled pick-up. You will also be asked to fill out questionnaires each week regarding you and your infant and daily updates on your infant's diet and health.

How will I be compensated?

Mothers will be provided with prenatal lactation consultation and 3 free private at-home lactation consultation visits on days 3 or 4, 7, and 15 after birth from one of the study's board certified Lactation Consultants. Participants will also receive \$100 worth of compensation in the form of **Target** or **Safeway** gift cards in two installments, \$50 on day 33 and \$50 on day 61.

Visit our **website** at: <http://ffhi.ucdavis.edu/hs/imprint-study> and **Facebook Page** at: <https://www.facebook.com/ffhi.imprint?ref=bookmarks>

For more information please contact the Study Coordinator, Melissa Breck (888) 217-5355 or (209) 252-9510 or email at: ucdavis.ffhi.clinicalstudies@gmail.com