If you are interested in this study, please ask your provider or contact one of our Research Coordinators - Anne, Michelle, or Chloe

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Are you thinking about getting an IUD after your baby is born?

Principal Investigator
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BLIS
Breastfeeding Levonorgestrel IUD Study

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What is the study about?
This research is studying how placing the Mirena intrauterine device (commonly called an IUD) right after birth affects how much women are breastfeeding 3 months later. The Mirena IUD is approved by the Food and Drug Administration to use as birth control with a good record of safety in breastfeeding women. We usually wait to put in this device until the 4th week after delivery or later. However, many women can’t come back for their visit after the baby is born but desire long-acting birth control that will not be permanent so they can have another baby later.

Putting in the IUD before a woman leaves the hospital after she has her baby is best for contraception. We wish to make sure that this practice does not affect a woman’s ability to successfully breastfeed her baby. Because we don’t have many studies on the effect of hormones on breastfeeding, this study seeks to determine if IUD placement prior to leaving the hospital has any kind of bad effect on milk production compared to if the IUD is placed 4-8 weeks after delivering a baby.

Information gained from this study will help in the treatment of future patients with understanding how an IUD affects breastfeeding.

What will happen if I participate?
You will be assigned by chance (like a flip of a coin) to receive either early insertion of the IUD or standard insertion of the IUD, so you will have an equal chance of receiving either procedure. This means that the IUD will be put in before leaving the delivery room (early insertion) and the other group will have the IUD put in at a clinic visit in 4-8 weeks (standard insertion).

You will have a physical examination, and your medical history related to your delivery and your baby will be reviewed. Information to be collected from your medical records includes your medical record number, information about how many times you have been pregnant and how many babies you have had as well as information about your delivery and about your infant at the time of delivery. We will collect contact information from you including telephone number, address, email, and two alternative contacts who can always get contact you. This information will be used to contact you for your follow ups. We will use the alternative contact numbers in case we are not able to reach you at your primary contact numbers. After your delivery, we will collect data on your contraceptive choices.

While you are in the hospital, we will collect information about you regarding your medical and pregnancy history. If you are in the "early insertion" group, a physician will put in your device before you leave the delivery room. If you are in the "standard insertion" group, you will have your IUD put in at a clinic visit 4-6 weeks after your baby’s birth.

As part of your participation in this study, we will contact you daily until your milk has come in. We will prepare you for the signs you will see when your milk comes in, and ask that you record the time this happens. We will also give you a diary to record days of bleeding for the study follow-up period as well as side effects and infant weights. We will call you 2 weeks after your baby’s birth to ask about your breastfeeding status, any supplements you feed the baby, return to sexual intercourse, and what kind of contraception you are using.

You will need to come for a clinic visit 4-8 weeks after your baby’s birth (if you are in the standard insertion group) to have the device inserted. At this time, if you received early insertion, you will have a pelvic exam (like getting a pap smear) to make sure the IUD is in the right place. You may need an ultrasound if the IUD strings are not visible. We will contact you every week until 10 weeks then every month for the first 6 months after your baby’s birth for a short interview by phone or electronic communication. At 3 & 6 months after your baby’s birth you will be asked to mail in your diary.

You will be eligible to receive merchandise cards for the inconvenience of participating in the study: $20 after the first follow-up visit $20 after the six-month phone contact

You may be able to participate if:

- You are interested in having an IUD placed after vaginal delivery.
- You are between 18 and 40 years old.
- You speak English or Spanish.
- Your provider tells you that you are able to safely use an IUD.

What are the risks or benefits to participating?
Every effort will be made to protect the personal information you provide. There is a small risk that your name will be identified with study data (for example, your pain scores or interview) that could cause you distress for whatever reason. Also, being a part of the study may be considered inconvenient by some women. There is no direct benefit to being in this study.