

The Progesterone Study

This study is being conducted by the fertility clinic at UNC Women's Hospital. This is a unique way to allow healthy women to help us create a model of infertility in a way that is safe and meaningful. We have utilized this same model in several previous studies, so we feel very confident in your ability to participate and experience few if any side effects. This research will help us to understand some specific aspects of infertility related to the hormone progesterone.

Basic requirements

- 18-35 years old
- having regular menstrual cycles (you get your period every 25-35 days)
- not taking hormonal birth control (pill, patch, depo-provera, nuva ring, etc.); no IUD's
- not pregnant now or trying to get pregnant in the next 2-3months
- not breastfeeding
- average body weight (BMI of 29 or less)
- don't have a history of pelvic infection or pelvic inflammatory disease or uterine fibroids
- other underlying medical conditions or medications considered case by case (example: anti-depressants are fine, but medications with hormone qualities may conflict)

What would I have to do?

This study takes 7-8 weeks to complete with a total of 8 visits to our clinic at UNC Women's Hospital. All appointments take between 20min-1hr.

The first step involves meeting with the study coordinator, Amy, to discuss what's involved in more detail so that you can decide if you are totally comfortable with the decision to volunteer. If you want to begin the study, you will sign consent forms and take home some ovulation test kits (similar to a home pregnancy test). The first step in the study is knowing when you ovulate, or release an egg from the ovary, during your menstrual cycle.

The next appointment happens ten days after a positive ovulation test. At this time you will be asked to start a medication called Lupron. The purpose is to (much like taking birth control pills) prevent you from ovulating for the next month. You will come back 10-14 days later for an ultrasound, a blood draw and then begin the using an estrogen supplement.

After another 10-14 days you will do another ultrasound and blood draw. You will add the third and final medication, which is progesterone. Now you are at the final stretch of the study! You will need to take the progesterone once a day for the next ten days. There are four more blood draws and, on the final day, you also will have an ultrasound, lavage and an endometrial tissue sample.

For going through all these steps, you will be compensated \$400. If you need to stop for any reason along the way, you will still receive partial compensation.

Why are these medications necessary?

Some women find they cannot get pregnant because they aren't ovulating properly. So, the first step in our model is to safely cause you to not ovulate for one cycle by using Lupron. This is similar to what birth control pills do only it works more quickly. However, taking Lupron causes your normal levels of estrogen and progesterone to fall- so the second piece of the model is to return estrogen to normal levels and for the progesterone to be at a normal or lower than normal levels.

What kind of side effects should I expect?

The consent form will list all possible side effects (we will talk about all these in more detail), but the ones most commonly described due to the medication are feeling tired or possibly PMS-like symptoms. Many women notice no change at all because we are simply keeping the hormone levels the same as they would be normally or, for some progesterone groups, lower than normal. This is easier to tolerate than taking high doses of these hormones.

Lupron is taken by a sub-cutaneous injection- this means a tiny needle is used to give the medication just underneath the skin, once a day. You could have some bruising. Estrogen is taken by a transdermal patch, so you could have some skin irritation. Progesterone is taken once a day for ten days by an intramuscular injection. You are likely to have some muscle soreness because of this.

The sample procedures (lavage and an endometrial tissue sample) may cause cramping similar to menstrual cramps and any discomfort typically passes within an hour.

Will any of this affect me later, when the study is over?

This is very unlikely. Again, much like taking birth control pills, once you discontinue the Lupron and hormone supplements your body will "re-set". Very quickly your hormone levels will return to normal, you will begin ovulating and start your period. Your ability to get pregnant later on will not be affected by taking the medications or by the sample procedures done on the final day.

I might consider doing this, what else should I know?

The key to this study is the ten days of progesterone- that is the heart of this study and it's really important. We will ask you to take the progesterone at a certain time of the day and also to come in for your last four blood draws at very specific times (right before or three hours after your scheduled progesterone dose time). We will work really hard to plan those times in a way that can fit with your schedule and hopefully inconvenience you as little as possible. You should consider: 1) are you comfortable having a pelvic exam (like when you see the gynecologist for a PAP smear)? 2) are you comfortable with needles? 3) do you have time and a somewhat flexible schedule that will allow you to come by our clinic for these 8 visits?

We are here to answer any questions you have about participating. Call or email the study coordinator, Amy Brown, 919-843-8621, obstudy@med.unc.edu, if you want to get involved. She can also put you in touch with doctors who can explain potential risks- we can only do this research project because it has been determined to be safe. Thanks!