

THIS BROCHURE INCLUDES
INFORMATION ABOUT A NEW RESEARCH
STUDY AND MAY HELP YOU DECIDE IF
YOU ARE INTERESTED IN BECOMING A
PARTICIPANT.

Sponsored by:

The Reproductive Medicine
Network and National
Institute of Child Health
and Human Development

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Do You Have Unexplained Infertility?

You may be eligible to participate in a research study.



Carolinas Medical Center
Women's Institute

Uncompromising Excellence. Commitment to Care.

www.cmc-womensinstitute.org

WHO IS ELIGIBLE FOR THE STUDY?

This research study is for women between the ages of 18 and 40 who have regular menstrual periods and have had difficulty conceiving for 12 or more months. Interested participants will go through a screening process to see if they qualify.

The screening will include:

- Blood work (checking hormone levels, kidney function and liver function)
- Hysterosalpingogram or sonohysterogram tests
- Pap smear and physical exam
- Semen analysis on male partner

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this four month randomized clinical trial is to identify a drug which helps couples successfully deliver a healthy child while reducing the rate of multiple gestations (twins, triplets, etc).

The study compares two oral fertility drugs, clomiphene and letrozole, and one injectable fertility drug, gonadotropin. Participants must be willing to accept randomization to either clomiphene, letrozole or gonadotropins. All women will then have intrauterine insemination timed to ovulation.

Treatment will be provided for up to four cycles or 20 weeks, unless pregnancy is achieved first. Pregnant subjects will be followed until viability is confirmed and pregnancy outcome is determined.

WHAT CAN I EXPECT IF I PARTICIPATE?

Participants will be asked to complete screening tests and questionnaires. After passing the screening, women will then be given one of three study drugs. This study is double blinded, meaning the doctor and patient will not know which of the three drugs are used. There are no placebos in this study.

Women will come to CMC Women's Institute while taking the study drug for monitoring with a transvaginal ultrasound and bloodwork until ovulation. An intrauterine insemination will be performed timed to ovulation.

WHAT COST IS COVERED BY THE STUDY?

Medication used to induce ovulation is free. All monitoring visits, blood tests, ultrasounds and inseminations are free.

WHAT COST IS NOT COVERED BY THE STUDY?

Pre-natal care during pregnancy and the delivery of your baby if you become pregnant are not covered by the study.

