

Scott & White Hospital & Clinics

Clinical Research at Scott & White

Study Title: "Prospective Comparison of Hormone Withdrawal Symptoms of a 24/4 Regimen with a 21/7 Regimen of OC"

Project ID#: 060783

Department: Obstetrics and Gynecology

Sponsor: Warner Chilcott

Brief Synopsis of the Study

Condition(s):	Treatment(s):
Hormonal Contraception	Comparing birth control pills on PMS; mood, headache and pelvic pain.

The purpose of this study is to assess hormone withdrawal symptoms in women while taking an oral contraceptive in the novel 24/4 (24 days of "real" pills) manner to taking pills in the standard 21/7 (21 "real" pills) manner. The birth control pills to be used in this study are monophasic (constant level of hormones for all "real" pill of the pack) pills that are currently marketed in the U.S. You will be one of approximately 55 subjects in this research study.

Who is eligible to participate in the study?

Age: 18 to 48 years of age

Gender: Females, who are currently taking the birth control pill, nuvaring or patch for at least 2 months.

What may be involved/required for subject participation? (Visits, tests and/or logs, etc.)s

The full duration of this study is approximately 8 months. There will be fourteen visits total. An initial visit will be required to sign consent, obtain basic information and explain the daily diaries. A total of eight visits, spaced three days apart, will require blood draws. These will take place during the 4th and 5th month of the study. Daily diaries must be returned during each research visit or by mail between scheduled visits. All women will begin the study with one month of Loestrin 1/20, to be taken in a normal 21/7 manner, and will complete a daily questionnaire. To continue in the study, you must be classified as having substantial fluctuation in your symptoms in relation to the

hormone free interval (week of “fake” pills) of this first cycle of pills. Of the women who continue in the study, half will be randomized to start taking Loestrin 24 Fe (24 real pills and 4 placebo pills), and half will continue taking Loestrin 1/20 in the standard 21/7 fashion for an additional 3 cycles. All women will be asked to continue keeping a daily log of their symptoms, which will be turned in to the study coordinator at each of the scheduled visits. Participants will not be given the choice initially as to which group they will be placed; however all women will be given the opportunity to evaluate the 24/4 regimen. One of the objectives of this study is to correlate the hormone withdrawal symptoms with actual hormone levels. Measuring hormones requires samples of blood. Over the course of the study, there will be a total of 8 separate blood samples taken from each participant.

For More Information Contact:

Coordinator(s): Iris Witt, RN, CCRP
Title(s): Clinical Research Nurse Coordinator
E-mail: iwitt@swmail.sw.org

Contact person: Monika Schwartz
Title(s): Research Services Assistant
Phone : 254-724-1350
E-mail: mschwartz@swmail.sw.org
