Clinical Trial ID:

NCT00000420

Title:

Safety of Estrogens in Lupus: Birth Control Pills

Summary:

Safety of Estrogens in Lupus Erythematosus - National Assessment (SELENA) is a study to test whether women with systemic lupus erythematosus (SLE or lupus) can safely use estrogen. We will determine this by looking at the effects of oral contraceptives (birth control pills, also known as "the pill") on disease activity and severity in women with SLE. The results of the study will show whether it is safe for women with SLE to use the pill.

Detailed Description:

This study tests the effect of exogenous female hormones on disease activity and severity in women with systemic lupus erythematosus (SLE). Physicians generally do not prescribe oral contraceptives (OCs) to women with lupus because of the widely held view that these drugs can activate SLE. This practice is based on the greater incidence of SLE in women

than in men, biologic abnormalities of estrogen metabolism, murine models of lupus,
several anecdotes of patients having disease flares while receiving exogenous hormones,
and a single retrospective study in patients with preexisting renal disease.

By contrast, recent retrospective studies suggest that the rate of flare is not significantly increased in patients taking OCs. The preexisting data is insufficient to warrant the dismissal of a potentially important birth control option in a disease that predominantly affects women in their reproductive years and whose fertility is not altered by the disease. Moreover, the use of OCs to preserve fertility in patients taking cyclophosphamide and the use of estrogens to prevent coronary artery disease and postmenopausal and steroid-induced osteoporosis are timely considerations.

We will attempt to define, in a multicenter, randomized, double-blind, placebo-controlled trial, the effect of OCs containing low-dose synthetic estrogens and progestins on disease activity in women with SLE. Because the research hypothesis is that OCs do not increase the risk of flares, we have designed the study to be able to detect

minimal

increases in the rate of flares in patients taking OCs.

We will enroll patients with inactive, stable, or moderate disease requiring less than

0.5 mg prednisone per kg of bodyweight per day over a 2-year period and randomize them to

receive birth control pills or placebo pills for 12 months. During that time, the patient

must use condoms or a diaphragm as birth control. We will recruit patients from clinics

and private practices that include over 4,000 women with SLE, most belonging to minority

groups.

Eligibility Criteria:

Inclusion Criteria:

- **Female**
- **Unequivocal diagnosis of SLE**
- **Inactive disease or be stable on 0.5 mg/kg/day or less of predisone**
- **Must be between 18 and 39 years old if non-smoker**
- **Must be between 18 and 35 years old if smoker**

Exclusion Criteria:

- **Blood pressure >145/95 on three occasions**
- **Deep vein, arterial thrombosis or pulmonary embolus**
- **GPL >40; MPL >40; APL >50; dRVVT >37 sec**
- **APL antibody syndrome ever**
- **Gynecologic or breast cancer**
- **Hepatic dysfunction or liver tumors**
- **Diabetes mellitus (NOT due to steroids) with vascular disease**
- **Congenital hyperlipidemia**
- **Complicated migraine**
- **Severe disease activity (SLEDAI >12)**
- **Increase in SLEDAI >2 points in 3 months**
- **Unexplained vaginal bleeding**

- **Use of estrogen (OCP) for >1 month at any time after SLE diagnosis**

- **Present pregnancy**

- **Angina or MI due to APS**

- **Age >35 yrs. for smokers; >39 yrs. for nonsmokers**

Gender:

Female

Minimum Age:

18 Years

Maximum Age:

39 Years

Phase:

Phase 3

Conditions:

- Systemic Lupus Erythematosus

Interventions:

- Ortho-Novum 777

Locations:

- UCLA Medical Center, Dept. of Rheumatology, Los Angeles, California

- University of Chicago Pritzker School of Medicine, Chicago, Illinois

- Louisiana School of Medicine, Dept. of Medicine/Immunology, Shreveport, Louisiana

- Johns Hopkins Hospital, Dept. of Rheumatology, Baltimore, Maryland

- Univ. of Michigan Med. Ctr., Rheumatology Division, Ann Arbor, Michigan

- Albert Einstein College of Medicine, Jacobi Hospital, Dept. of Rheumatology, Bronx, New York

- Hospital for Joint Diseases, New York, New York

- Hospital for Special Surgery, Dept. of Rheumatology, New York, New York

- UNC Medical Center, Dept. of Rheumatology, Chapel Hill, North Carolina

- Oklahoma Medical Research Foundation, Oklahoma City, Oklahoma

- Univ. of Pennsylvania Medical Center, Philadelphia, Pennsylvania

- Univ. of Pittsburgh, Dept. of Rheumatology, Pittsburgh, Pennsylvania

- University of Texas Health Sciences Center, Houston, Texas

- Medical College of Virginia, Richmond, Virginia

- Medical College of Wisconsin, Milwaukee, Wisconsin