Clinical Trial ID:

NCT00000419

Title:

Safety of Estrogens in Lupus: Hormone Replacement Therapy

Summary:

Safety of Estrogens in Lupus Erythematosus - National Assessment (SELENA) is a study to test whether postmenopausal women with systemic lupus erythematosus (SLE, or lupus) can safely use the hormone estrogen. In this part of the study, we will look at the effects of estrogen replacement therapy on the activity and severity of disease in women with SLE.

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 hormone replacement therapy (HRT) to women with SLE because of the widely held view that such treatment 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 HRT.

We will examine, in a multicenter, randomized, double-blind, placebo-controlled trial, the effect of hormonal replacement with conjugated estrogens on disease activity in postmenopausal women with SLE. We will recruit patients from clinics and private practices that include over 4,000 women with SLE, most belonging to minority groups.

We will give patients hormones for 1 year.

NOTE: This trial has been terminated as of August 2002 upon recommendation of the Data Safety Monitoring Board (DSMB), based on the findings of the WHI Trial. Study subjects have discontinued study drug but will continue followup visits to study doctors through May 2003

Eligibility Criteria:

Inclusion Criteria:

- **Female**

- **Unequivocal diagnosis of SLE**

- **Inactive disease or stable on 0.5 mg/kg/day or less of prednisone**

- **Chemical evidence of menopause or have stopped periods for at least 6 months**

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 (HRT or OCP) for >1 month at any time after SLE diagnosis**

- **FSH <40**

- **Premenopausal myocardial infarction**

Gender:

Female

Minimum Age:

18 Years

Maximum Age:

85 Years

Phase:

Phase 3

Conditions:

- Systemic Lupus Erythematosus

Interventions:

- Premarin and Provera

Locations:

- UAB Medical Center, Birmingham, Alabama

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

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

- Louisiana School of Medicine, Shreveport, Louisiana

- Johns Hopkins Hospital, Baltimore, Maryland

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

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

- Hospital for Joint Diseases, New York, New York

- Hospital for Special Surgery, 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, Ambulatory Care Center, Richmond, Virginia

- Medical College of Wisconsin, Milwaukee, Wisconsin