



A Study Invitation from Health in Our Hands and Tulane University

Dear Health in Our Hands member,

You are invited to participate in a research study being conducted through Tulane University Health Sciences Center. The research study is called BIM (Bazedoxifene/Conjugated Estrogens (BZA/CE) Improvement of Metabolism).

The BIM study is looking at a medication called Conjugated Estrogens/Bazedoxifene (CE/BZA), which is currently approved in the United States under the name Duavee for treatment of symptoms of menopause. The purpose of this study is to determine if the medication can reduce body fat and improve metabolism in clinically obese postmenopausal women during a short study of 3 months. The drug is taken once daily by mouth in the form of a tablet. Based on your medical history, you may qualify for this study.

The study will last about 3 months, with a total of 5 visits to the research center. At study visits, you will be asked to provide blood and urine samples, complete questionnaires, do a physical examination and electrocardiogram (ECG that measures the electrical activity of the heart) and have Dual-energy x-ray absorptiometry (DEXA) Scan to measure belly fat. For all study visits you will be financially compensated for your time and travel. During your participation in the study we will follow you closely to monitor for any changes in your health and report any important information to you and your doctor(s).

To qualify for the study, you must be a female, between ages 50-60, overweight or clinically obese (BMI 27-45), entered into menopause within the last 5 years, and have hot flashes. If you have a history of heart disease (heart attack, stroke, or bypass and stent surgery), diabetes, breast cancer or have had hysterectomy (removal of your uterus) you will not be eligible for the study.

Your participation in this study is entirely up to you. Whether or not you decide to participate will not affect the medical care you receive at your current hospital. If you are interested in participating or would like to know more about the study, please contact Bonnie Katalenich at 504-988-6200.

Sincerely,

The Health in Our Hands Team