

Clinical Trial for Hormone Therapy in Postmenopausal Women with Coronary Heart Disease

Background

The Heart and Estrogen/progestin Replacement Study (HERS) was a randomized, double-blind, placebo-controlled trial designed to test the efficacy and safety of estrogen plus progestin therapy for prevention of recurrent coronary heart disease (CHD) events in women. The study participants consisted of 2,763 women who were younger than 80 years, postmenopausal with an intact uterus, and had high risk of CHD events at the time of enrollment. The clinical trial had two treatment arms: hormone therapy and placebo. Study subjects were randomly assigned to one of the two treatment arms and were followed for at least 4 years. For more information about the design and baseline characteristics of the HERS clinical trial, see the article by Grady et al. (Controlled Clinical Trials, 19:314–335; 1998) that is available from the following website:

http://faculty.washington.edu/tathornt/Controlled_Clinical_Trials_HERS_Study_1998.pdf

For this project, we are interested in the effect of hormone therapy on plasma lipid biomarkers for CHD after one year of treatment. In particular, it is of primary interest to assess the effects of hormone therapy on cholesterol levels and triglyceride levels at the end of year 1 in this clinical trial for hormone therapy replacement.

Questions of Interest

The data to be analyzed for this project is a subset of the data collected from the 2,763 women in the Heart and Estrogen/progestin Replacement Study (HERS) clinical trial of hormone therapy. The questions to be addressed are:

1. What associations exist between the plasma lipid biomarkers for CHD at baseline (i.e., prior to randomized treatment assignment) and the available data on participant demographics (age, race, BMI), behavior (smoking, alcohol consumption, physical activity), and available clinical and laboratory measures of organ system functioning (e.g. glucose, blood pressure)?
2. Is there any evidence of hormone therapy treatment effects on the plasma lipid biomarkers after one year of treatment?
3. Is there any attenuation of the hormone therapy treatment effects after adjustment for known risk factors for CHD?
4. Do any of the hormone therapy treatment effects identified above for the plasma lipid biomarkers differ according to race/ethnicity, statin medication use, smoking behavior, or alcohol consumption.

Available Data

These data come are a subset of the data collected on the 2,763 women in the Heart and Estrogen/progestin Replacement Study (HERS) clinical trial of hormone therapy. The data are stored in the file "HERSdatasub.csv" and this file includes demographic information and clinical measurements of study subjects at the time of study enrollment (and before assignment to hormone treatment) as well as clinical measurements on study subjects after 1 year on an assigned treatment arm. When data is missing for a particular variable, 'NA' is recorded. The descriptions of the variables are as follows:

<i>HT</i>	Hormone therapy arm assignment ("hormone therapy", "placebo")
<i>age</i>	Age in years of the subject at the time of study enrolment
<i>raceth</i>	Subject's race/ethnicity ("African American", "White", "Other")
<i>statins</i>	Statin medication use by subject at the time of enrolment ("no", "yes"). Statins are a class of drugs often prescribed by doctors to help lower cholesterol levels in the blood. Statin is a medication prescribed to reduce LDL cholesterol.
<i>smoking</i>	Current smoker at the time of enrollment ("no", "yes")
<i>drinkany</i>	Any alcohol consumption at the time of enrollment ("no", "yes")
<i>exercise</i>	Subject self-report for exercising at least 3 times a week at the time of enrollment ("no", "yes")
<i>diabetes</i>	Subject previously diagnosed with diabetes ("no", "yes")
<i>SBP</i>	Baseline systolic blood pressure, measured in mmHg, is the maximum pressure generated during a contraction of the heart muscle. Persons with high blood pressure have been found to be at increased risk for heart disease, cerebrovascular disease, and kidney disease. A "normal" systolic blood pressure is less than 120 mmHg.
<i>DBP</i>	Baseline diastolic blood pressure, measured in mmHg, is the maximum pressure generated When a heart muscle is between contractions. Persons with high blood pressure have been found to be at increased risk for heart disease, cerebrovascular disease, and kidney disease. A "normal" range diastolic blood pressure is less than 80 mmHg.
<i>BMI</i>	Body mass index (BMI) of the subject measured at the time or study enrollment. BMI is expressed in units kg/m^2 and is body mass (measured in kilograms) divided by the square of body height (measured in meters).
<i>BMI.1</i>	Measure of BMI for subject after 1 year on the assigned treatment arm.
<i>glucose</i>	Fasting glucose measurement of the subject at the time of enrollment. This is a measurement of the amount of a sugar called glucose from a blood sample. Glucose is measured in milligrams per deciliter (mg/dL).
<i>glucose.1</i>	Measure of glucose for subject after 1 year on the assigned treatment arm.
<i>LDL</i>	Baseline LDL (low density lipoprotein) cholesterol measurement of the subject at the time of enrollment. LDL cholesterol, measured in mg/dl units, is often referred to as "bad cholesterol", because persons with high levels of LDL have been found to have higher risk of heart disease.
<i>LDL.1</i>	Measure of LDL cholesterol level for subject after 1 year on the assigned treatment arm.
<i>HDL</i>	Baseline HDL (high-density lipoprotein) cholesterol measurement of the subject at the time of enrollment. HDL cholesterol, measured in mg/dl units, is often referred to as "good cholesterol", as it removes harmful bad cholesterol from where it doesn't belong, and high HDL levels reduce the risk for heart disease.
<i>HDL.1</i>	Measure of HDL cholesterol level for subject after 1 year on the assigned treatment arm.
<i>TG</i>	Baseline triglyceride level measurement of the subject at the time of enrollment. Triglycerides, measured in mg/dl units, are a type of lipid found in blood. Individuals with high triglycerides levels have been found to have higher risk of heart disease.
<i>TG.1</i>	Measure of triglyceride level for subject after 1 year on the assigned treatment arm.