Outline of a Study

Element	Example
Title	Effects of Hormone Treatment after Menopause on Liprotein (a) (Lp(a))
Research question	What are the effects of treatment with estrogen plus progestin (compared with placebo) on Lp(a) levels in postmenopausal women?
Significance	1. Epidemiologic studies suggest that hormone treatment after menopause may help prevent coronary heart disease, the largest cause of death in women 2. Lp(a) is an understudied lipoprotein that has been found to be an independent risk factor for coronary disease in several studies. 3. Among conventional lipid-lowering drugs, only nicotinic acid in high doses lowers Lp(a) levels; however, previous studies have suggested that hormone treatment may have this effect. 4. There is a need to confirm this finding for the estrogen plus progestin treatment that is now commonly used after menopause, and to extend it to women with existing coronary disease.
Design	Randomized blinded trial with one year follow-up.
Subjects	
Entry criteria	Postmenopausal women with documented coronary disease (evidence for prior myocardial infarction or coronary artery surgery, or 50% obstruction on angiography).
Recruitment	Consecutive sample of all women who qualify in 20 clinical centers, recruited in cardiology clinics and by mailings and advertisements.
Variables	
Predictor	Randomization to a daily tablet containing conjugated equine estrogen (0.65 mg) and medroxy-preogesterone acetate (2.5 mg), or to a placebo identical in appearance.
Outcome	Change in serum level of Lp(a) between baseline and 1 year after randomization, measured immunochemically with a sandwich ELISA assay that uses a monoclonal antibody to apo(a) as the capture antibody (Strategic Diagnostics, Newark, DE).
Statistical issues	
Hypothesis	There will be a greater decrease in Lp(a) levels in the hormone-treated group than in the placebo group.
Sample size and power	The number of women in the existing HERS trial available for this ancillary study was 2,763. This allows detection of a reduction in Lp(a) of 2 mg/dL with a power of 90%, using a t-test and two-tailed alpha of 0.05.

FINER Criteria for a Good Research

Feasible

Adequate number of subjects
Adequate technical expertise
Affordable in time and money
Manageable in scope

Interesting

To the investigator

Novel

Confirms or refutes previous findings
Extends previous findings
Provides new findings

Ethical

Respect for person
Beneficence/nonmaleficence
Justice

Relevant

To scientific knowledge
To clinical and health policy
To future research directions