

ARIC MANUSCRIPT PROPOSAL FORM

Manuscript #267

1. Title:

Estrogen and Diabetes

2. Writing Group (list individual with lead responsibility first):

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3. Timeline:

Begin: Spring, 1994

Draft completed: September 30, 1994

4. Rationale:

The majority of epidemiologic studies have shown a 35% to 45% reduction in cardiovascular (CVD) deaths in women taking postmenopausal hormone replacement therapy (HRT). Even though the results of randomized, controlled trials are not yet available, it is currently recommended that HRT prophylaxis be considered for all postmenopausal women (Grady et al., *Ann Intern Med* 1992; 117:1016-37). The mechanisms whereby HRT may protect against CVD are only beginning to be understood. HRT appears to beneficially affect the lipid profile (raising HDL-cholesterol, lowering LDL-cholesterol) as well as reducing various coagulation factors (fibrinogen, antithrombin III) (Nabulsi et al., *NEJM* 1993; 328:1069-75). However, the effect of HRT in various high-risk subpopulations, such as women with diabetes is unknown. Diabetic women are at 5 to 6 times higher risk of CVD events than age-matched non-diabetic women (Manson et al., *Arch Intern Med* 1991; 151:1141-7). No data exists on the effect of HRT on the lipid profile or coagulation parameters of diabetic women. In fact, HRT could have a deleterious effect on the already high triglyceride levels found in diabetic women.

5. Main Hypothesis:

Estrogen and estrogen + progestin will have similar magnitudes of association with the lipid and coagulation parameters of diabetic compared to non-diabetic women.

Diabetic women receiving HRT have risk factor profiles similar to that of diabetic women who have not received HRT.

6. Data (variables, time window, source, inclusions/exclusions):

Visit 1 cross-sectional analysis.

Independent variables: hormon01, diabts02

Lipids: trgsiu01, apasiu01, apbsiu01, ldl02, hdl02, hd2slu02, hd3siu02, ldlsiu02, hdl01, hdl201, hdl301, lipa01, lipa02, lipa06, lipa07, lipa08

Coagulation factors: hema07, hema09, hema11, hema13, hema15, hema17

Covariates: bmi01, wsthpr01, elevel02, race, sprt_i01, center, cigt01, vlage01, inssiu01, glucos01, drnk01, roseic03,

cholmd02, msra08a, msra08f, hom54, hom10d, chma16, sbpa21, cigtyr01

Include: postmenopausal women (menops01), of any race (racegrp), who were fasting at baseline (fast0802), and not

currently taking lipid lowering medication (cholmd01); May have prevalent CHD (prvchd04).