



Kronos Early Estrogen Prevention Study

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BASELINE CHARACTERISTICS OF WOMEN ENROLLED IN THE KRONOS EARLY ESTROGEN PREVENTION STUDY (KEEPS)

V.M. Miller¹, F. Naftolin², D.M. Black³, E.A. Brinton⁴, M. Cedars³, R.A. Lobo⁵, J.E. Manson⁶, G.R. Merriam⁷, N. Santoro⁸, H.S. Taylor⁹, S.M. Harman¹⁰

¹Mayo Clinic, Rochester, MN, USA; ²NYU College of Medicine, New York, NY, USA; ³U of CA School of Medicine, San Francisco, CA, USA; ⁴U. of Utah Medical School, Salt Lake City, UT, USA; ⁵Columbia College of Physicians and Surgeons, New York, NY, USA; ⁶Harvard Medical School, Boston, MA, USA; ⁷U. of Washington School of Medicine, Seattle, WA, USA; ⁸Albert Einstein College of Medicine, Bronx, NY, USA; ⁹Yale University School of Medicine, New Haven, CT, USA; ¹⁰Kronos Research Institute, Phoenix, AZ, USA

Objective: The Women's Health Initiative (WHI) hormone trials did not confirm data from observational studies showing that menopausal hormone therapy (MHT) reduced the risk of coronary heart disease (CHD). Two variables that differed between WHI and observational studies were the chronological age and proximity to menopause at which women initiated therapy. KEEPS is a randomized, double-blinded trial designed to test the hypothesis that MHT started early in menopause will reduce progression of atherosclerosis defined by carotid intimal medial thickness and coronary calcification. This evaluation compared baseline characteristics of KEEPS participants to those in the WHI.

Design and Method: KEEPS enrolls women 42-58 years old between 6-36 months from their final menses. Exclusion criteria include hysterectomy, body mass index (BMI) > 35 kg/m², LDL cholesterol >160 mg/dL, coronary calcification >50 Agatston Units, diabetes, and history of myocardial infarction, stroke, thromboembolic disease or cancer and smoking >10 cigarettes/day. Before randomization, serum chemistries and blood counts are measured and a physical exam performed. Baseline characteristics of WHI participants were obtained from the published literature (Ann. Epidemiol. 13:S78-S86, 2003).

Results: Of women meeting eligibility criteria for KEEPS (n=660), the average age is 53±2.5 years compared to 63 years for women in the WHI. Ethnicities are comparable in the two studies with about 80% Caucasian. Of women in the WHI, 64% had a systolic blood pressure (SPB) >120 mmHg; vs. 46% in the KEEPS (KEEPS mean=119±15 mm Hg).



KEEPS

Sponsored by

Kronos Longevity Research Institute

2390 East Camelback Road
Suite 440

Phoenix, Arizona 85016-3452

PH. (866) 878-1221 • FAX: (602) 778-7490

www.keepstudy.org

Eighty percent of women in KEEPS are never smokers compared to 50% in the WHI. BMI and all lipid parameters are significantly ($p < 0.01$) lower in KEEPS participants than those in WHI. Framingham risk score (FRS) show approximately 4-fold greater 10-year CHD risk in WHI women (Table).

Conclusion: As planned, women enrolled in KEEPS have significantly fewer conventional risk factors for cardiovascular disease than women in the WHI. KEEPS will provide important information regarding the impact of MHT started soon after menopause, as is typically the case in clinical use, on atherosclerosis progression in relatively healthy women.

	BMI (Kg/m ²)	Cholesterol (mg/ dL)			Triglyceride (mg/dL)	FRS ^b 10 yr risk (based on SBP of 135 mmHg)
		Total	HDL	LDL		
KEEPS (n = 660)	26.2±4.6 ^a	215.3±31.8	62.8±3.9	129.9±29.2	91.2±51.0	1%
WHI all	29.1±6.0 (n=27,347)	223.7±38.2 (n=2311)	54.9±13.8 (n=2311)	135.7±34.9 (n=2311)	135.7±63.6 (n=2311)	3-6%
WHI (E + P)	28.5±5.4 (n=16,608)	222.0±37.1 (n=1319)	55.3±13.6 (n=1319)	134.7±32.9 (n=1319)	130.9±59.4 (n=1319)	3-6%

^aData presented as mean±SD.

^bFramingham Risk Score calculated from mean data by NCEP calculator