



Kronos Early Estrogen Prevention Study

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BASELINE COGNITIVE AND DEMOGRAPHIC CHARACTERISTICS OF WOMEN ENROLLED IN THE KEEPS (KRONOS EARLY ESTROGEN PREVENTION STUDY) COGNITIVE AND AFFECTIVE STUDY.

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Objective : The KEEPS (Kronos Early Estrogen Prevention Study) Cognitive and Affective Study (KEEPS C/A) is a multisite, randomized, placebo-controlled, double-blind, parallel-group design addressing major hormone-related issues raised by recent findings of WHIMS. The objective of the KEEPS C/A Study is to evaluate differential efficacy of oral conjugated equine estrogen (CEE or Premarin®) and transdermal 17 β -estradiol (tE2) with 12 days/month progesterone (Prometrium®) on mood and cognition in healthy non-hysterectomized, women who are within 6 months - 3 years of menopause. The KEEPS C/A Study will be conducted over 4 years.

Participants and Methods: Outcome measures include cognitive and mood tests administered at baseline and months 18, 36 and 48 during treatment. Of these, month 36 evaluation investigates potential progestational effects while months 18 and 48 examine estrogenic effects. Affective measures include: Profile of Mood States Questionnaire (POMS), Memory Function Questionnaire (MFQ), Beck Depression Inventory (BDI) and PRIME-MD. The cognitive battery includes: Prospective Memory Test, Modified Mini-Mental State Examination (MMSE2), NYU Paragraphs, Stroop, Digit Symbol, WMS-3 Letter-Number Sequencing, California Verbal Learning Test 2 (CVLT-2), Mental Rotation, Visual Search, Benton Visual Retention Test and Verbal Fluency.

Results: To date, the KEEPS C/A Study has enrolled 671 women, average age (mean \pm SD) 53.7 \pm 2.5 years. Approximately 77% of subjects are Caucasians, while 23% are of minority origin. Most participants report an annual income over \$40,000 and have at least a high school diploma.



KEEPS

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At baseline, mean BMI is 26.2 ± 4.6 kg/mm², laboratory values (mg/dL) are: Total cholesterol 215 ± 31.8 , HDL cholesterol 65.0 ± 17.2 , LDL cholesterol 129.9 ± 29.3 , triglycerides 91.2 ± 51.0 , and fasting glucose 89.0 ± 9.9 . All women are cognitively healthy (MMSE2 = 28.9 ± 2.1). Interestingly, a positive relationship ($r = .150$, $p < .01$) is observed between plasma estradiol and MMSE2 total score.

Conclusions: Baseline physiological, cognitive and affective data in the KEEPS C/A Study indicate that the cohort is healthy and free of cognitive dysfunction. The correlation between estradiol and MMSE score supports prior data reporting estradiol's salutary effect on cognition.