

Women's Health Initiative estrogen plus progestin clinical trial: A study that does not allow establishing relevant clinical risks

Aedo, Sócrates

Cavada, Gabriel

Blümel, Juan E.

Chedraui, Peter

Fica, Juan

Barriga, Patricio

Brantes, Sergio

Iribarra, Cristina

Vallejo, María

Campodónico, Ítalo

© 2015 by The North American Menopause Society. Objective: This study aims to determine time differences (differences in restricted mean survival times [RMSTs]) in the onset of invasive breast cancer, coronary heart disease, stroke, pulmonary embolism, colorectal cancer, and hip fracture between the placebo group and the conjugated equine estrogens 0.625 mg plus medroxyprogesterone acetate 2.5 mg group of the Women's Health Initiative (WHI) trial based on survival curves of the original report and to provide adequate interpretation of the clinical effects of a given intervention. Methods: Distribution of survival function was obtained from cumulative hazard plots of the WHI report; Monte Carlo simulation was performed to obtain censored observations for each outcome, in which assumptions of the Cox model were evaluated once corresponding hazard ratios had been estimated. Using estimation methods such as numerical integration, pseudovalues, and flexible parametric modeling, we determine