

STATEMENT ON WOMENS HEALTH INITIATIVE STUDIES

Study Design: Randomized controlled primary prevention trial for coronary heart disease

Study groups:

Estrogen + Progesterone: 16,000 post menopausal women (age 50-79) randomized to either Prempro or placebo

Estrogen alone: 10,739 post menopausal women (age 50-79) randomized to either Premarin .625 or placebo

Medications used: Prempro (.625 mg Premarin + 2.5 mg medroxyprogesterone acetate) or Premarin .625

Results: In May 2002 Estrogen + Progesterone arm was ended . In February 2004 Estrogen alone arm ended.

Details:

Adverse Event	Estrogen + Progesterone	Number of cases per 10,000 women	Estrogen Alone	Number of cases per 10,000 women
	Increased		Increased	
Coronary heart disease	29%	7	NS	
Breast cancer	26%	8	Note *	
Stroke	41%	8	39%	12
Pulmonary embolism	113%	8	NS	
Total CV disease	22%		12%	
Total cancer	3%		NS	
	Decreased		Decreased	
Colorectal cancer	37%	6	NS	
Endometrial cancer	17%		NA	
Hip fracture	34%	5	39%	6
Death due to other causes	8%		NS	
Combined fractures	24%		30%	
Total mortality	2%		NS	

* slight but statistically insignificant **decreased risk** with estrogen alone

Bottom Line: Neither Estrogen + Progestin nor Estrogen alone should be started or continued *solely for prevention of chronic disease*. Most postmenopausal women take HRT for a variety of other reasons such as relief of hot flashes, vaginal dryness, insomnia, mood swings, prevention or treatment of osteoporosis. If you take HRT, in particular Prempro or Premarin a good way to think about the **overall increased risk of adverse events as listed above is: 2/1000 women with Estrogen + Progesterone** **2/10,000 women with Estrogen alone**

References:

Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women Principal Results From the Women's Health Initiative Randomized Controlled Trial JAMA. 2002; 288:321-333.

Effects of Conjugated Equine Estrogen in Postmenopausal Women with Hysterectomy. The Women's Health Initiative Randomized Controlled Trial. JAMA.2004; 291:1701-1712.

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