WELL-HART (estrogen-progestin) 2003

NCT00000559

1 Treatments

**Studied treatment**  17 beta-estradiol plus sequentially administered medroxyprogesterone acetate
1 mg of oral micronized 17 beta-estradiol daily plus 5 mg of medroxyprogesterone acetate daily for 12 consecutive days of every month

**Control treatment**  placebo

**Concomittant treatments**

**Age (years)**  63.5 y

**Age (years)**  -

2 Patients

**Patients**  Postmenopausal women with angiographically-documented coronary disease

**Inclusion criteria**  postmenopausal (serum estradiol level below 20 pg per milliliter), 75 years of age or younger, low-density lipoprotein (LDL) cholesterol level of 100 to 250 mg per deciliter (2.59 to 6.46 mmol per liter) and a total triglyceride level of less than 400 mg per deciliter (4.52 mmol per liter), at least one coronary-artery lesion occluding 30 percent or more of the luminal diameter.

**Exclusion criteria**  more than 15 cigarettes per day, breast cancer or gynecologic cancer within the five years, life-threatening disease and projected survival of less than five years, diastolic blood pressure of more than 110 mm Hg, fasting serum glucose concentration of more than 200 mg per deciliter, thyroid disease, serum creatinine level of more than 2.5 mg per deciliter (220 ìmol per liter), congestive heart failure (Killip class III or IV and ejection fraction below 30 percent), more than five hot flashes per day that interfered with their daily activities, plans to undergo a coronary-artery revascularization procedure within six months after the first screening visit, baseline coronary angiogram that had been obtained before or less than six months after a revascularization procedure, myocardial infarction less than six weeks before

**type of prevention**  secondary

**diabetes (%)**  50%

**hypertension (%)**  -

**hyperlipidemia (%)**  -

**BMI (kg/m²)**  30.2

**Hysterectomy (%)**  44%
Oophorectomy (%) 25.7%  

3 Methods  
Blinding double blind  
Design -  
Centers 5  
Geographical area USA  
Sizes 74/76  

4 Results  

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
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<th>95% CI</th>
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<tbody>
<tr>
<td>stroke</td>
<td>-/74</td>
<td>-/76</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>venous thromboembolism</td>
<td>-/74</td>
<td>-/76</td>
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<tr>
<td>PE</td>
<td>-/74</td>
<td>-/76</td>
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<tr>
<td>all cause death</td>
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<td>4/76</td>
<td>0,77</td>
<td>[0,17; 3,57]</td>
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<td>CV events</td>
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<td>16/76</td>
<td>1,16</td>
<td>[0,54; 2,48]</td>
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<td>Cv death</td>
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<td>Coronary events (CHD)</td>
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<td>non fatal MI</td>
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<td>-/76</td>
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5 References  