

Table 2.3. Randomized controlled trials of estrogen-only menopausal therapy and breast cancer

| Reference, location, name of study | Cohort description | Exposure assessment | Organ site (ICD code) | Exposure categories | No. of cases/deaths | Relative risk (95% CI)* | Adjustment for potential confounders | Comments |
|--|--|--|------------------------|--|----------------------|---|---|----------|
| Porch et al (2002) USA 1993–2000 Women’s Health Study | 17 835 apparently healthy postmenopausal women aged \geq 45 years, followed prospectively for an average of 5.9 years. Breast cancer occurred in 411 women. Women selected from the Women’s Health Study. | Self-reported questionnaire | Breast cancer | ERT <5 years \geq 5 years | 101 33 68 | 0.96 (0.65–1.42) 0.96 (0.58–1.58) 0.99 (0.65–1.53) p-trend = 0.31 | Age, age at menopause, menopause type, age at menarche, nulliparity, age at first pregnancy, abortions/miscarriages, full-term pregnancies, ever use of oral contraceptives, history of benign breast disease, use of breast cancer screening, family history of breast cancer, race, body mass index, cigarette use, alcohol use, and exercise | |
| Anderson et al (2004) USA | A randomized, double-blind, placebo controlled disease prevention trial (the estrogen-alone component of the WHI) conducted in 40 US clinical centers beginning in 1993. Enrolled were 10 739 postmenopausal women, aged 50–79 years, with prior hysterectomy, including 23% of minority race/ethnicity. | Participants received either 0.625 mg/d of conjugated equine estrogen (CEE) (n=5310) or placebo (n=5429) | Invasive breast cancer | CEE by age group (years) 50–59 60–69 70–79 | 94 25 42 27 | HR (95% CI) 0.77 (0.59–1.01) 0.72 (0.43–1.21) 0.72 (0.49–1.07) 0.94 (0.56–1.60) | Age, prior disease, randomization status in the dietary modification trial | |