

Table 2.3. Randomized clinical trials of adjuvant and chemopreventive use of tamoxifen and endometrial cancer

Reference, country	No. of patients and treatment ^a	Dose of tamoxifen (mg/day)	Duration (years)	Median follow-up (years)	No. of endometrial cancers	Risk ratio (95% CI)	Comments	
Fisher et al. (1996), United States and Canada	1404	Tamoxifen	20	10	10	21	-	Double blind trial. Half of those allocated to tamoxifen were randomized at 5 years to continue or change to placebo.
	1414	Placebo				3		
	570	Placebo				3	-	
	583	Tamoxifen	20	5	10	6		
Delozier et al. (2000), France, Belgium and Argentina	1882	Tamoxifen long-term	20	10–12	4 years post randomization	13	-	Patients randomized who were disease-free after 2 to 3 years of adjuvant tamoxifen treatment
	1991	Tamoxifen stopped after 2–3 years	20	2–3		12		
Rutqvist and Johansson (2007), Sweden	1364	Tamoxifen	40	2 (see comment)	18	33	-	796 subjects disease-free at 2 years were randomized to tamoxifen for another 3 years vs no further tamoxifen
	1374	No tamoxifen				4		

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The Early Breast Cancer Trialists' Collaborative Group (1998), (International)	14 813	Tamoxifen	20 (some)	1–5	Up to 10	92	2.58 (1.9–3.3)	Pooled analysis of 55 randomized trials, including 37 000 women, that began before 1990, comprising about 87% of the worldwide evidence then available.
	14 588	Control	30–40 (others)			32		
Braithwaite et al. (2003), (International)	Total: 52 929	Tamoxifen	Mean: 21.8	Mean: 4.3	Mean 5.6	Total: 185	2.70 (1.94–3.75)	Meta-analysis of 32 trials (breast cancer risk reduction and treatment trials were included.)
		Control						
Cuzick et al. (2003), (International)	14 214	Tamoxifen (for chemoprevention)	20	5–8	10	53	2.4 (1.5–4.0)	Overview analysis of four chemoprevention trials, and updated meta-analysis of nine treatment trials
	14 192	Control				22		
	7085	Control	20–40	3 years or longer	15	41	3.4 (1.8–6.4)	
	7085	Tamoxifen (for treatment) Control				12		

^a Observation: patients receiving no adjuvant therapy