

Table 2.4. Randomized clinical trials of adjuvant use of tamoxifen and contralateral breast cancer

Reference, country	No. of patients and treatment ^a		Dose of tamoxifen (mg/day)	Duration (years)	Median follow-up (years)	Number (rate/1000) contralateral breast cancers	Risk ratio (95% CI)	Comments
Fisher et al. (1996), United States and Canada	1404	Tamoxifen	20	10	10	56 (5.0)	[0.62]	
	1414	Placebo				82 (8.0)		
Delozier et al. (2000), France, Belgium and Argentina	1882	Tamoxifen long-term	20	10–12	4 yrs post	27	-	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	randomization	44		
Rutqvist & Johansson (2007), Sweden	1364	Tamoxifen	40	2 (see comment)	18	70	-	796 subjects disease-free at 2 years were randomized to tamoxifen for another 3 years vs no further tamoxifen
	1374	No tamoxifen				100		

Table 2.4. Randomized clinical trials of adjuvant use of tamoxifen and contralateral breast cancer

Reference, country	No. of patients and treatment ^a		Dose of tamoxifen (mg/day)	Duration (years)	Median follow-up (years)	Number (rate/1000) contralateral breast cancers	Risk ratio (95% CI)	Comments
The Early Breast Cancer Trialists' Collaborative Group (1998), (International)	14 813	Tamoxifen	20 (some)	1–5	Up to 10	369	0.70	Overview analysis of 55 trials.
	14 588	Control	30–40 (others)					
Cuzick et al. (2003), (International)	7085	Tamoxifen	20–40	3 years or longer	15	105	0.54 (0.43–0.69)	Overview analysis of nine treatment trials.
	7085	Control						

^a Control patients received no adjuvant therapy