Appendix 4: Trials investigating varenicline (page 1 of 2)

Study	Sample size*	Design	Country	Mean CPD	Smoking abstinence (%)							
					6 Months				12 Months			
					Point prevalence		Continuous		Point prevalence		Continuous	
					Active	Control	Active	Control	Active	Control	Active	Control
Gonzales 2006[1]	696	R, DB, PC, MC	USA	21	34	18	NR	NR	29	14	NR	NR
Jorenby 2006[2]	685	R, DB, PC, MC	USA	22	35	15	NR	NR	31	17	NR	NR
Nakamura 2007 iii*†‡[3]	310	R, DB, PC, MC	Japan	24	47	34	41	29	42	27	36	23
Nakamura 2007 ii*†‡[3]	309	R, DB, PC, MC	Japan	23	47	34	38	29	40	27	33	23
Nakamura 2007 i*†‡[3]	307	R, DB, PC, MC	Japan	24	48	34	39	29	43	27	31	23
Tsai 2007[4]	250	R, DB, PC, MC	Taiwan & Korea	23	57	29	47	22	NR	NR	NR	NR
Nides 2006 i*§[5]	249	R, DB, PC, MC	USA	21	NR	NR	10	7	NR	NR	8	5
Nides 2006 ii*§[5]	249	R, DB, PC, MC	USA	21	NR	NR	10	7	NR	NR	6	5
Nides 2006 iii*§[5]	248	R, DB, PC, MC	USA	20	NR	NR	21	7	NR	NR	15	5
Oncken 2006 i*‡¶[6]	259	R, DB, PC, MC	USA	21	NR	NR	NR	NR	22	5	18	4
Oncken 2006 ii*‡¶[6]	259	R, DB, PC, MC	USA	21	NR	NR	NR	NR	35	5	25	4
Oncken 2006 iii*‡¶[6]	258	R, DB, PC, MC	USA	21	NR	NR	NR	NR	26	5	19	4
Oncken 2006 iv*‡¶[6]	258	R, DB, PC, MC	USA	21	NR	NR	NR	NR	24	5	19	4

CPD = cigarettes per day, R = randomized, DB = double-blind, PC = placebo controlled, MC = multi-center, NR = not reported.
References appear on the next page.
*Number of subjects included in the analysis.
†Patients in the RCT by Nakamura were randomized to 0.5 mg/day of varenicline (i), 1.0 mg/day of varenicline (ii), or 2.0 mg/day of varenicline (iii), or placebo. Data from the same placebo arm were used for all comparisons.
‡Results obtained in part through correspondence.
§Patients in the RCT by Nides were randomized to 0.3 mg (i), 1 mg (ii), or 2 mg (iii) of varenicline, or placebo. Data from the same placebo arm were used for all comparisons.
¶Patients in the RCT by Oncken were randomized to titrated 1 mg/day (i), titrated 2 mg/day (ii), non-titrated 1 mg/day (iii), and non-titrated 2 mg/day (iv). Data from the same placebo arm were used for all comparisons.

References to Appendix 4 (page 2 of 2)

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6. Oncken C, Gonzales D, Nides M, et al. Efficacy and safety of the novel selective nicotinic acetylcholine receptor partial agonist, varenicline, for smoking cessation. *Arch Intern Med* 2006;166:1571-7.