

Evaluation of toxicity of oral capsule administration of PSK in randomised controlled trials (RCT)

Study design	Subjects (n)	Dose	Duration on PSK	Toxicity due to PSK	Refs.
RCT	967	3g/day	2 yrs	Not observed	Toi (1)
RCT	262	3 g/day	82 mons	Not observed	Nakazato (2)
RCT	207	3 g/day	2 yrs	Not observed	Ohwada (3)
RCT	441	3 g/day (4 wks on and 4 wks off)	84 wks	Not observed	Ito (4)
RCT	448	3g/day	3 yrs	Not observed	Mitomi (5)
RCT	525	3 g/day	2 yrs	Not observed	Morimoto (6)
RCT	224	3g/day	1 yr	Not observed	Sugimachi (7)

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3. Ohwada S, Ikeya T, Yokomori T, Kusab T, Roppongi T, et al. Adjuvant immunotherapy with oral tegafur/uracil plus PSK in patients with stage II or III colorectal cancer: a randomised controlled study. *Bri J Cancer*. 2004; 90: 1003-1010.
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patients with StageII breast cancer: 5-year results from the Nishinishon co-operative study group of adjuvant chemoendocrine therapy for breast cancer (ACETBC) of Japan. *Eur J Cancer*. 1996; 32A(2): 235-242.

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