Clinical Studies on Hochu-ekki-to®

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Karibe, 1997	Effect on Methicillin Resistant Staphlococcus Aureus (MRSA) carriers	C n=44	Not stated	Not stated	Hochu-ekki-to® (TJ-41)	Subjects did not receive any other treatment such as vancomycin or other antibiotics, and MRSA readings were negative for 61.6% of the patients receiving Hochu-ekki-to® (61.6%). Hochu-ekki-to® significantly reduced the time necessary to achieve a negative MRSA reading; 47.0 +/- 5.5 days compared to 88.4 +/- 12.8 days for the control group.
Kuratsune *et al*., 1997	Chronic fatigue syndrome	DB, PC n=9	8 to 12 weeks	7.5 g per day	Hochu-ekki-to® (TJ-41)	On the Performance Status (PS) scale, 34.5% of the patients improved 3 or more levels in the PS scale, to the degree comfortable living became possible. A high level of improvement was reported in symptoms such as fatigue, exhaustion, low-grade fever, muscle pain, and mental alertness.
Niwa *et al*., 1996	Immune function in post-operative patients with gastrointestinal (GI) cancer	Cm n=25	8 wks	7.5 g per day	Hochu-ekki-to® (TJ-41)	Immune function was measured using blood assays of NK and LAK activity. Significant activity was found regarding NK activity, from 29.9% pre-treatment to 42.2% after 8 weeks. LAK activity did not change. Improvement was observed in appetite, fatigue, and diarrhea.
Igarashi *et al*., 1995	Effect on anorexia, fatigue, and malaise	MC n=45	4–12 weeks, average of 10.5	5.0–7.5 g per day	Hochu-ekki-to® (TJ-41)	In a subjective evaluation, 88.9% of patients reported improved or markedly improved symptoms. All 25 atonic constitution patients reported their symptoms as improved or better.
Mori *et al*., 1992	Fatigue accompanying chemotherapy	R, Cm n=43	5 weeks, 1 wk prior to chemotherapy, 4 wks after chemotherapy	2.5 g, 3 times per day before meals or control	Hochu-ekki-to® (TJ-41)	Patients receiving TJ-41 (the Tsumura code this formula) had less fatigue, better appetite, and improved mood without side effects. Results were based upon patient evaluation and records kept by physicians and nurses. TJ-41 did not show any effect on nausea or vomiting compared to control. The study concluded that TJ-41 had a significant effect in the prevention of fatigue in cancer chemotherapy.

KEY: C – controlled, **CC** – case-control, **CH** – cohort, **CI** – confidence interval, **Cm** – comparison, **CO** – crossover, **CS** – cross-sectional, **DB** – double-blind, **E** – epidemiological, **LC** – longitudinal cohort, **MA** – meta-analysis, **MC** – multi-center, **n** – number of patients, **O** – open, **OB** – observational, **OL** – open label, **OR** – odds ratio, **P** – prospective, **PB** – patient-blind, **PC** – placebo-controlled, **PG** – parallel group, **PS** – pilot study, **R** – randomized, **RC** – reference-controlled, **RCS** – retrospective cross-sectional, **RS** - retrospective, **S** – surveillance, **SB** – single-blind, **SC** – single-center, **U** – uncontrolled, **UP** – unpublished, **VC** – vehicle-controlled.