Clinical Studies on Padma® 28

Intermittent Claudication

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Sallon *et al.*, 1998	Intermittent claudication	R, PC, DB n=83	6 months	2 capsules, twice daily or placebo	Padma® 28	Padma® 28 improved pain-free walking distance (58%), changes in ankle systolic pressure (mean of 12.5%) and its recovery time (0.8 min.) compared to pre-treatment values. Study conculded that Padma® 28 may be an effective treatment option for intermittent claudication.
Mehlsen *et al.*, 1995	Intermittent claudication	R, DB, PC n=86	4 months	2 capsules, twice daily or placebo	Padma® 28	After 1 month and throughout the study, the treated patients obtained improvements in pain-free and maximum walking distance (115 m to 227 m; p<0.001) compared to placebo.
Smulski and Wojcicki, 1995	Intermittent claudication	R, DB, PC n=100	4 months	2 capsules, twice daily or placebo	Padma® 28	Patients showed a significant (p<0.01) increase of maximum walking distance from 87.5 to 187.5 meters in treatment group compared to a nonsignificant increase of 12.5 meters in placebo group. The formula was found to be significantly more effective at increasing walking distance after 12 weeks (p<0.01) and 16 weeks (p<0.01) compared to placebo, without side effects.
Winther *et al.*, 1994	Intermittent claudication	R, DB, PC n=36	4 months	Two, 340 mg tablets, twice daily	Padma® 28	The treatment group showed an oxidative burst response of monocytes after stimulation with zymozan decreased. Neither group demonstrated a significant change in platelet aggregation in vitro. Padma® 28 increased fibrinolytic activity, measured by a more than 40% shortening of the ECLT and a drop in the level of PAI-1.
Drabaek *et al.*, 1993	Intermittent claudication	R, DB, PC 2 groups of 18 patients each n=36	4 months	2 capsules, twice daily or placebo	Padma® 28	The maximum distance walked (115m–227m) and the distance walked without pain (52m–86m) was significantly longer (p<0.05) with Padma® 28 without side effects.
Samochowiec *et al.*, 1987	Intermittent claudication (PAOD stage II)	R, DB, PC n=100	4 months	2 capsules, twice daily or placebo	Padma® 28	The treatment group showed an increase in walking distance of 78 meters (98%; p<0.001) and a significant reduction (p<0.5 or more) in levels of cholesterol, triglycerides, total lipids (-10%), and betalipoproteins (-18%).
Schrader *et al.*, 1985	Intermittent claudication	R, PC, DB n=43	4 months	3 capsules twice daily or placebo	Padma® 28	Padma® 28 increased the distance walked (>100 vs. 27 meters) compared to placebo. The distance walked without pain was greater with Padma® 28 but not statistically significant. No side effects were observed.

Other

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Samochowiec *et al.*, 1992	Hypercholesterolaemia and hypertriglyceridemia	C n=52	16 weeks	Two, 380 mg capsules, twice daily	Padma® 28	Padma® 28 demonstrated a statistically significant effect in both groups. The triglycerides decreased from 284 mg/dL to 160 mg/dL in the hypertriglyceriemia group, and the cholesterol was lowered from 271 mg/dL to 210 mg/dL in the hypercholesterolemia group.
Jankowski *et al.*, 1991	Respiratory Tract Infections (recurring)	C n=19 (ages 2 to 4)	2 months	1 tablet, three times daily	Padma® 28	In 12 children (63.1%), Padma® 28 significantly increased (85%) the spontaneous bactericidal activity of blood serum against 3 bacterial strains; *Salmonella typhimurium* 568, and *Escherichia coli* strains 044 and 055. In 4 children, the activity increased slightly (21%) and 3 children (15.7%) showed no effect.
Wojcicki and Samochowiec, 1986	Angina Pectoris	C, DB, PC n=50	2 weeks	2 capsules, twice daily or placebo	Padma® 28	80% of the patients obtained a good or excellent clinical response. The mean number of anginal attacks was reduced from 37.5 to 11.5 during treatment with Padma® 28 (p<0.001), and treatment significantly reduced (p<0.001) the amount of nitroglycerin tablets used. The platelet aggregation threshold increased by 125% and exercise tolerance improved significantly (p<0.001).

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.