

A MULTI-CENTER, SELF-CONTROLLED STUDY OF CHOLESTIN IN A MULTI-CENTER, SELF-CONTROLLED STUDY OF CHOLESTIN IN SUBJECTS WITH ELEVATED CHOLESTEROL.

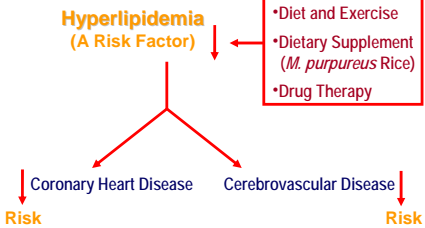
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ABSTRACT

A traditional Chinese food and medicine, red yeast rice (Cholestin™) was evaluated in a multi-center, self-controlled, open-label study in 187 subjects (116 men, 71 women) with mildly to moderately elevated total cholesterol (TC) and LDL cholesterol (LDL-c). Eligible subjects were placed on the AHA Step 1 Diet throughout the study. After 4-weeks of this diet, Cholestin (2.4 g/day) was given for 8 weeks. Lipid profiles were determined at Week 4 (4 weeks of diet), and at Week 8 and 12 (4 and 8 weeks of Cholestin treatment), and at Week 14 (2 weeks after discontinuing Cholestin). The diet alone for 1 month had no effect on serum cholesterol. The 8-week treatment with Cholestin reduced TC by 16.4%, LDL-c by 21.0%, triglycerides (TG) by 24.5%, and ratio of total:HDL cholesterol by 17.7%, and increased HDL cholesterol (HDL-c) by 14.6%. Discontinuation of Cholestin following the Cholestin treatment led to a relatively rapid return of serum lipids to pre-study levels at Week 14. Product-related adverse reactions were mild or moderate in severity. Thirty-four patients (18%) were judged to have adverse reactions possibly or probably related to Cholestin treatment. The reported adverse events were headache, abdominal bloating, and gas. This multi-center clinical trial at 12 U.S. sites confirmed that treatment with a traditional Chinese food, Cholestin, was well tolerated and was effective in reducing TC, LDL-c, TG, and ratio of TC:HDL-c, and in increasing HDL-c in patients with hyperlipidemia.

Introduction



红曲米 (Red Yeast Rice) (Monascus purpureus Went Rice)

- Widely used as a food supplement in China and other Asian countries for centuries: for the preparation of fish, meat, and bean curd, and in the making of rice wine
- Used in traditional Chinese food and medicine
 - To improve blood circulation
 - To promote healthy digestive functions



Methods

A 12-Center, Open-Label Clinical Study



* American Heart Association Step 1 diet alone

Cholestin™ was supplied by PHARMANEX, In., Simi Valley, CA

Inclusion Criteria:

- Total cholesterol: 200 - 280 mg/dL
- LDL-cholesterol: 135 - 190 mg/dL

Baseline Characteristics of Patients

	n	Age (years)	Body weight (kg)
Total	187	54 ± 0.8	78 ± 1.0
Male	116	52 ± 0.9	85 ± 1.0
Female	71	58 ± 1.2	67 ± 1.1
(M : F)	1.6 : 1)		

Blood Lipids after Diet and Cholestin™ Treatment

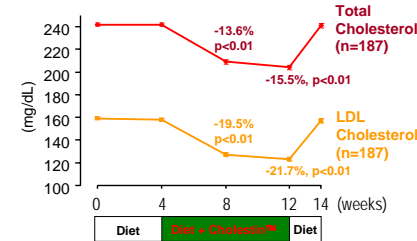
	Total cholesterol (mg/dL)	LDL cholesterol (mg/dL)	Triglycerides* (mg/dL)	HDL cholesterol [®] (mg/dL)
Baseline	242 ± 1.2	158 ± 1.1	264 ± 8.2	35.3 ± 0.6
4-week diet [®]	242 ± 1.3	158 ± 1.2	248 ± 8.4	35.9 ± 0.8
4-week Cholestin™	209 ± 2.0**	127 ± 1.7**	217 ± 11**	37.9 ± 0.9**
8-week Cholestin™	204 ± 1.8**	123 ± 1.7**	202 ± 10**	39.7 ± 1.0**
2-week diet [®]	240 ± 2.1	157 ± 2.0	247 ± 12	36.5 ± 1.0

[®] American Heart Association Step 1 Diet alone

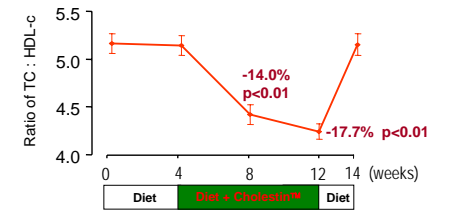
[®] Stratified based on pretreatment triglycerides (>200 mg/dL; n=63) or HDL-c (≤ 40 mg/dL for men, or ≤ 45 mg/dL for women; n=54).

** p<0.01, compared to baseline.

Changes in Total and LDL Cholesterol



Changes in Ratio of Total : HDL Cholesterol



Side Effects

- Mild GI discomfort: 8 cases (4.3%)
- Headache: 2 cases (1.1%)
- No changes in liver or renal functions

Dropout

Total dropout: 25 cases (13.4%)

Summary



- ↓ Total cholesterol by 15.5%
- ↓ LDL-cholesterol by 21.7%
- ↓ Triglycerides by 21.9%
- ↑ HDL-cholesterol by 13.6%

Conclusion

- Cholestin™ is a safe and highly effective dietary supplement in maintaining normal blood lipids in the general population.
- >90% of patients responded to Cholestin™ treatment with a reduction in their blood lipids.