

## 4. Metabolism and Endocrine Diseases

### Reference

Kim TK, Jung WS, Park SU, et al. Comparison of efficacy and safety between Chunghyul-dan (HH-333) and Atorvastatin (Lipitor®). *Daehan-Hanbang-Naegwa-Hakhoeji (Korean Journal of Oriental Internal Medicine)* 2003; 24(4): 837–45 (in Korean with English abstract).

### 1. Objectives

To compare the efficacy of Chunghyul-dan (清血丹) with that of atorvastatin (Lipitor®) in lowering lipid levels.

### 2. Design

Randomized controlled trial (RCT).

### 3. Setting

One Oriental hospital and one Western hospital (2 hospitals) (Kyunghee University Medical Center), Republic of Korea.

### 4. Participants

Sixty-two hyperlipidemia patients with total cholesterol level of over 240 mg/dl or LDL-cholesterol level of over 160 mg/dl.

### 5. Intervention

Arm 1: Low-dose Chunghyul-dan (清血丹) treatment group (n=33). Treatment with chunghyul-dan for 8 weeks (2 capsules per day).

Arm 2: High-dose Chunghyul-dan (清血丹) treatment group (n=16). Treatment with Chunghyul-dan for 8 weeks (4 capsules per day).

Arm 3: Atorvastatin treatment group (n=13). Treatment with atorvastatin (10 mg per day).

### 6. Main outcome measures

- 1) Total cholesterol, low density lipoprotein (LDL)-cholesterol, high-density lipoprotein (HDL)-cholesterol, triglyceride, total lipid, and phospholipid levels.
- 2) Aspartate aminotransferase (AST), alanine aminotransferase (ALT), blood urea nitrogen (BUN), and creatinine levels.

### 7. Main results

- 1) Chunghyul-dan (both doses) and atorvastatin significantly decreased total cholesterol, LDL-cholesterol, total lipid, and phospholipid levels.
- 2) There were no significant between or among-group differences in total cholesterol, LDL-cholesterol, HDL-cholesterol, triglyceride, total lipid, and phospholipid at the end of the trial.
- 3) Low and high doses (2 and 4 capsules, respectively) of Chunghyul-dan produced similar decreases in outcome measures.

### 8. Conclusions

Treatment with Chunghyul-dan and atorvastatin can decrease levels of blood lipids. No adverse events or side effects were observed, suggesting the safety of Chunghyul-dan as treatment for hyperlipidemia.

### 9. Safety assessment in the article

Chunghyul-dan and atorvastatin were not associated with hepatotoxicity or nephrotoxicity. There were no significant between-group differences between the two groups in biochemical parameters including AST, ALT, BUN and creatinine.

### 10. Abstractor's comments

In this study, the therapeutic effect of Chunghyul-dan on serum lipids was comparable to that of the conventional hyperlipidemia drug, atorvastatin. Although this clinical trial used a Western drug control instead of a placebo control and involved comparing patients who were not randomized, it is suggested that the lipid lowering effect and safety of Chunghyul-dan was demonstrated and can be regarded as a clinical basis for using the drug to treat hyperlipidemia.

### 11. Abstractor

Lee BC, 28 May 2010.