

## **Cholesterol and triglyceride-lowering effect of two spice preparations - a pilot study**

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### **Contributions and interests:**

Eva Lydeking- Olsen designed the study, analysed data and wrote the paper together with Janne Springborg Clewlow. Vita Damsoe and An-Mari Mey Hansen took care of data accrual and contributed to the writing of the paper.

Senior statistician Martin Eeg, Medicon, supervised the statistical analysis.

Institute for Optimum Nutrition, Holistic Therapy and Research is a private non-profit institute, independent of MB Pharmos and none of the authors are affiliated with MB Pharmos.

The sponsor and supplier of the study approved the study protocol, but had no role in data analysis, data interpretation or writing of the report.

## **Abstract**

### **Background**

Hypercholesterolemia is a well established risk factor for ischemic heart disease that can be addressed in several ways. Use of non-pharmacologic dietary supplements is of potential benefit in addressing hypercholesterolemia.

### **Objective**

Two herbal products were investigated for their potential cholesterol-lowering effect.

### **Methods**

#### *Design and subjects*

A 24-week, double-blind study with 20 participants of which 19 were included in the analysis. Table 1 shows baseline characteristics. U85-2 contained tannin, cayenne pepper and vanillin and U100-3 turmeric, ensian root, hot paprika and vanillin. At inclusion plasma cholesterol was > 6 mmol/l, or with one or more risk factors: > 5 or 4.5mmol/l respectively. Previous dietary patterns (mean fat-energy %: 34) and physical activity levels were maintained during the study.

#### *Data collection*

Data were obtained by interview, aided by semiquantitative questionnaires and 7-d records of food intake, analysed by Dankost 2000 computersoftware.

Analysis of blood lipids was performed on freshly drawn blood at weeks 0 and 24 following overnight fasting. Total cholesterol, HDL cholesterol and triglycerides were measured by a standard enzymatic technique at a precision of 2%, 6% and 3%, respectively, at Nova Medical Medilab (Copenhagen, Denmark), which has GLP status. LDL cholesterol values were calculated by the Friedewald equation  $LDL = TC - HDL - (TG/5)$ .

#### *Analysis*

Data were entered into Excel<sup>®</sup> and analysed by the SAS<sup>®</sup> 8.2 statistics package (SAS INC, Cary, USA) and StatXact 5. The effect of dietary supplements on cholesterol values was evaluated by a non-parametric test, the Wilcoxon test for paired differences, as data were not normally distributed. A two-sided p value < 0.05 was considered significant. The randomisation code was not broken until final analysis had been performed.

### **Results**

U100-3 had a significant effect with a decrease of 16% in non-HDL cholesterol and a close to significant effect with a decrease of 13% in Total cholesterol and a borderline significant effect with a decrease of 16% in LDL cholesterol. Ratios between the atherosclerotic (total and LDL) cholesterol and the protective HDL cholesterol improved by 11% (TC:HDL ratio) and 14% (LDL:HDL ratio) for U100-3. The U85-2 showed no effects. Results are summarized in table.

### **Conclusion**

The U100-3 preparation has a beneficial and clinically relevant long term effect and should be investigated further for treatment of mild to moderate hypercholesterolemic individuals.

**Keywords** : hypercholesterolemia, spice preparation, paprika, turmeric, vanilla, gentian

**Table 1 Baseline characteristics<sup>1)</sup>**

Variable	U85-2	U100-3
	(n = 10)	(n = 9)
Age (years)	55.5 ± 14.5 (33 - 74)	64.0 ± 8.8 (47 - 77)
Height (m)	1.71 ± 0.1	1.74 ± 0.07
Weight (kg)	78.2 ± 11.2	77.7 ± 14.6
BMI (kg/m <sup>2</sup> )	26.9 ± 3.4 (22.4 - 32.8)	25.6 ± 3.4 (21.1 - 30.5)
Current smokers (number)	1	1
Previous smokers (number)	3	6
Antihypertensive therapy (number)	2	1
Energy consumption (KJ/day)	8946 ± 3077 (5,340 – 14,562)	9902 ± 2403 (7,470 – 13,814)
<i>Energy%</i>		
- Fat	33.9	33.8
- Protein	15.8	15.6
- Carbohydrate	46.2	41.6
- Alcohol	4.1	9.0

1) mean ± SD, range in parenthesis. The two groups showed no statistically significant difference between the variables

**Table 2: Lipid concentrations in subjects treated with the spice preparations**

Parameter	Start		Week 24		Difference from start to week 24				
	Mean	SEM	Mean	SEM	Mean	SEM	Pct change in means	Test statistic (2)	Two sided exact p value (2)
<i>U-100-3, n= 9</i>									
Total Cholesterol	7.77	0.54	6.77	0.43	-1.00	0.56	-13	-16.5	0.055
HDL Cholesterol	1.66	0.13	1.66	0.13	0.00	0.04	-0.0	-1.00	1.000
LDL Cholesterol <sup>1)</sup>	5.77	0.51	4.82	0.45	-0.95	0.54	-16	-16.5	0.051
Non-HDL Cholesterol	6.11	0.51	5.11	0.44	-1.00	0.55	-16	-17.5	0.035
Triglyceride	1.70	0.17	1.43	0.21	-0.27	0.19	-16	-10.5	0.238
Total Cholesterol : HDL ratio	4.86	0.40	4.34	0.50	-0.52	0.30	-11	-14.5	0.098
LDL <sup>1)</sup> : HDL ratio	3.64	0.39	3.12	0.45	-0.52	0.28	-14	-15.5	0.074
<i>U-85-2, n=10</i>									
Total Cholesterol	6.83	0.23	6.64	0.26	-0.19	0.30	-2.8	-5.50	0.541
HDL Cholesterol	1.60	0.14	1.66	0.15	0.06	0.07	3.8	7.50	0.480
LDL Cholesterol <sup>1)</sup>	4.89	0.26	4.69	0.30	-0.20	0.29	-4.1	-6.50	0.539
Non-HDL Cholesterol	5.23	0.27	4.98	0.31	-0.25	0.29	-4.8	-8.00	0.443
Triglyceride	1.70	0.28	1.45	0.24	-0.25	0.23	-15	-6.50	0.477
Total Cholesterol : HDL ratio	4.56	0.43	4.44	0.41	-0.12	0.20	-2.7	-6.00	0.574
LDL <sup>1)</sup> - HDL ratio	3.31	0.38	3.07	0.33	-0.24	0.18	-7	-6.50	0.557

Units are mmol/L.

1) LDL cholesterol calculated using the Friedwald equation:  $LDL = TC - HDL - TG/5$ .

2) Test used: Wilcoxon Signed Rank Test for paired differences on the difference from start to week 24.