



**HEDRON ANALYTICAL INC**

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## A Pilot Clinical Trial to Determine the Efficacy of Strauss Heartdrops on Blood Cholesterol and Pressure.

### **Abstract:**

The effects of Strauss Heartdrops was tested on 10 subjects in the age range 20 – 67 years. None of the subjects were regular users of herbal preparations for high cholesterol or hypertension and none were regular users of any of the herbs contained in the Strauss preparation or extracts containing those actives. Fasting blood cholesterol levels were examined at the beginning and the end of the 2 month trial. Initially, the blood cholesterol levels were between 160 – 250 mg% and decreased significantly over the two month study period compared to a control group where no change was observed.

In addition, blood pressure measurements taken at specific points after the daily ingestion of the Heartdrops indicated a significant decrease in this value within five hours of administration. Both of these findings indicate a beneficial effect of Strauss Heartdrops on two major factors which contribute to heart disease. Further clinical trials of this product are warranted.

### **Introduction:**

More than 2,000 testimonials claim the benefits of Strauss Heartdrops as the “cure for heart disease”, although this product has never been subjected to the rigors and scrutiny of a proper clinical trial. Pilot clinical trials point the way for more extensive clinical work and, indeed, lend validity to the product under testing as preliminary data is built.

In this study, we looked at two major contributing factors to heart disease risk, cholesterol and blood pressure, and attempted to accumulate data regarding the efficacy of the Heartdrops on these two parameters. Since hypercholesterolemia has frequent association with ischemic heart disease and this process can, in turn, lead to high blood pressure, curtailing of hypercholesterolemia even in persons without this disorder would be expected lead to a reduced risk to heart disease.

Since the Heartdrops are a mixture of herbs, containing as many as six different actives, these were studied as a whole, rather than focusing on one of the actives. Preliminary work on the product using High Pressure Liquid Chromatography (HPLC) had demonstrated the quality of the product in terms of very consistent levels of Allicin, considered an active from the herb garlic contained in the mixture. Based on the consistency of Allicin within the product, we consider the Heartdrops to be made with sufficient quality control measure in place to guarantee consistency of product from bottle to bottle and batch to batch.

## **Materials and Methods**

This study utilized 10 volunteers who do not routinely take any herbal preparations with actives directed at cardio-vascular disease. These include herbs such as garlic, cayenne pepper, hawthorn and onions. All of the volunteers were in good health with no apparent disease. The subjects were randomly divided into two groups, 6 as experimental and 4 as controls. The experimental subjects were asked to administer the Heartdrops as prescribed on the product: "shake first, then 3 x daily put 15 drops under your tongue and hold for one minute and swallow". They were asked to continue this regime for 2 months. The controls went about their usual routines, avoiding onions and garlic in their diets. At the beginning and the end of the study fasting blood samples were taken and total blood cholesterol determinations made. A one tailed paired 't' test was applied to verify statistical significance of the accumulated data.

Total cholesterol was determined by HPLC, employing a Hewlett Packard 1090 LC series II with diode array detector using a method modified from Duncan et al. (1). Blood pressure was determined with a standard apparatus, consisting of pressure cuff and stethoscope.

In attempts to gain some knowledge on the effects of Heartdrops on blood pressure, two of the volunteers with the highest sitting blood pressure readings were monitored after beginning the Heartdrops regime at bi-hourly intervals for their first day of the study.

## **Results**

Before beginning the regime of Heartdrops the blood cholesterol level of the experimental group ranged between 160-250 mg%. Values such as these would be considered normal (Health Canada Report, 1999). After 2 months with a consistent intake of Heartdrops the blood cholesterol levels of the experimental group dropped significantly with the average decrease per subject found to be 31 mg %. This is a decrease of roughly 15% of the initial level of this group and was also significant ( $p < 0.001$ ). The control group, by comparison, showed an average decrease of 1.6 mg% which was not statistically significant, and essentially represents no change. Comparing the experimental group to the control demonstrated a significant decrease in total blood cholesterol in the experimental group ( $p < 0.05$ ).

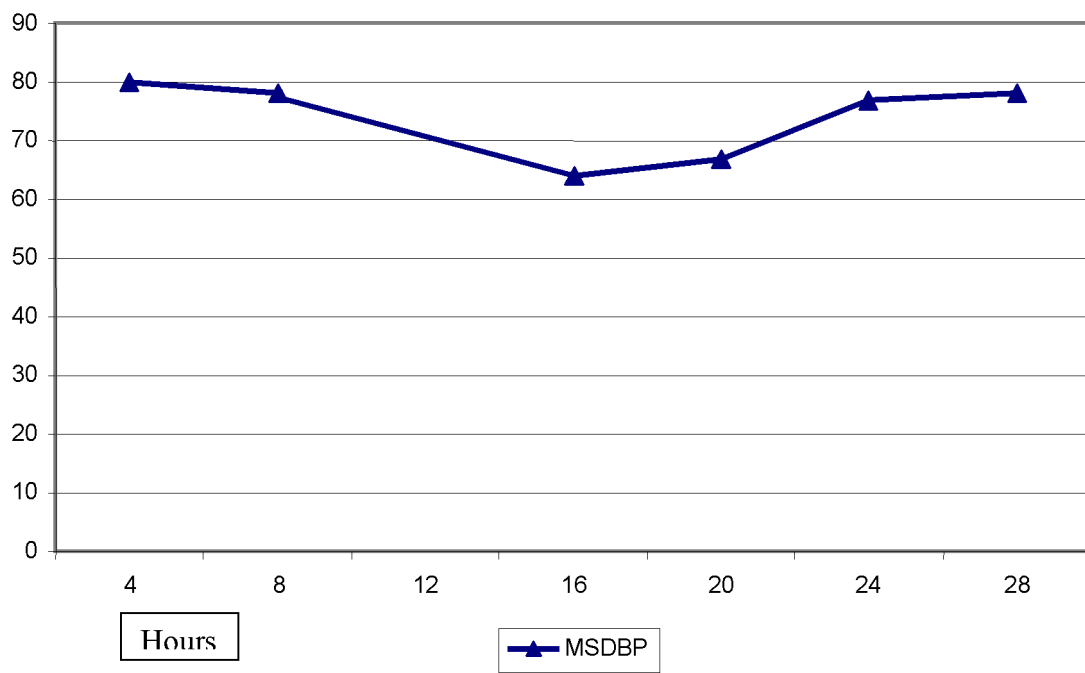
In addition, to the rather dramatic effects of the Heartdrops on blood cholesterol a definite trend in lowering blood pressure was observed in the two subjects studied. This occurred between 5-14 hours after administration of a large dose of Heartdrops (3x15 drops as single dose). The average decrease in diastolic blood pressure was 6/15 +/- 3/2 mm Hg in the sitting position.

None of the subjects complained of any side effects, odor or nausea during any of the studies.

**Table 1: The effect of Strauss Heartdrops on serum cholesterol levels**

Parameter	Experimental Group n=6			Control Group n=4		
	Before	60 days	Difference	Before	60 days	Difference
Mean (mg%)	220 +/- 51	188 +/- 25	32 +/- 15	210 +/- 28	208 +/- 24	2 +/- 8
Decrease			15%			0.9%
Statistics			(p<0.001) significant			(p>0.10) non-significant

**Figure 1**  
Mean Sitting Diastolic Blood Pressure After a Single High Dose of Strauss Heartdrops®



**Discussion:**

Pilot Clinical Trials are designed to show the way to larger, more complex and much more expensive clinical trials. Although they are not intended to prove efficacy or safety they will often build data which lends strong evidence on these accounts. Such is the case in this pilot study which lends statistically sound scientific data to the Strauss Heartdrops product particularly to its ability to lower blood cholesterol. In the results section we see that the Heartdrops lowered the blood cholesterol levels in all of the volunteers tested over a two month period. Cholesterol not only showed a downward trend but averaged out as a 15% decrease in blood cholesterol for each subject tested. The difference between the experimental group and the decrease seen in the control group of 0.9% is statistically significant. What this means is that ingesting the prescribed dose of the Heartdrops on a daily basis can lower blood cholesterol by more than 30%. A proposed follow-up study would increase the number of persons in the test and control groups and include more severe cholesterol levels such as those above 250 mg%. Based on the data collected in this study one would expect even more marked effects where cholesterol levels are already elevated.

Reduction of blood cholesterol has a proven relationship with reduced risk to many forms of cardio-vascular disease, including hypertension, artherosclerosis, thrombosis and stroke. High levels are considered a definite risk factor. From the data presented here it is reasonable to conclude that using the daily prescribed dosage of Strauss Heartdrops will decrease a person's risk of developing or suffering from cardio-vascular disease.

In addition, the experiment on blood pressure included in this study is also indicative of the beneficial effects of the Heartdrops in lowering risk to heart disease. With an average, again statistically significant, 15 point, decrease in blood pressure among the individuals receiving the Heartdrops, strongly implies the products efficacy in reducing risk.

In conclusion, based on the data accumulated in this pilot trial, Strauss's Heartdrops appears to be an effective medicine for the treatment of heart disease. By significantly lowering the levels of two major risk factors, both in relatively short time frames, an efficacious product is indicated. In addition, none of the subjects involved in the study experienced any side-effects, lending more credibility to its safety.

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