

RANDOM MULTI-CENTER EVALUATION TO TEST THE EFFICACY OF PHASEOLUS VULGARIS (PRECARB) IN OBESE AND OVERWEIGHT INDIVIDUALS

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Summary

Objective: To test the efficacy of Pre Carb (phaseolus vulgaris) as an aid in the treatment of obesity and overweight in Mexican patients, specifically on the border, in the city of Tijuana, Baja California, Mexico. People of any city of origin were included, with different types of eating habits and customs; they did not follow a special diet during the study.

Methodology: The study was conducted in the city of Tijuana, Baja California, with 50 patients who were classified as overweight, class-I obesity, class-II obesity and morbid obesity, ages ranging from 18 to 75 years, who were given Precarb (Natrol's Carb Intercept 500 mg. capsules) to test its efficacy as a treatment aid for reducing body weight in adults. The study ran for 30 days in which they took 1 gram of Precarb (2 capsules), 3 times per day with high-carbohydrate meals, with no special diet. In addition to body weight, body mass index (BMI), waist-to-hip ratio (WHR), cholesterol and triglycerides were also evaluated, all of which are important risk factors for the obese patient.

Results: Of the patients evaluated, 74% completed the study, of which 98% obtained positive results by reducing their body weight by 1.8 kg to 3.6 kg during the first 30 days, with no special eating regimen and with no additional exercise; no adverse reactions or gastrointestinal discomfort was reported.

It is important to mention that although there was a reduction of 1.8 kg to 3.8 kg, 10 individuals who received nutritional counseling, increased their physical activity and adhered to the study indications, markedly reduced their body weight and their cholesterol levels and triglycerides. The two most significant changes were: a) reduction of body weight of 12 kg, a decrease in cholesterol levels from 434 mg to 143 mg and a decrease in triglyceride levels from 248 mg to 190 mg; b) reduction of glucose levels from 200 mg to 149 mg in 30 days. Six percent (3 individuals) of patients were dropped due to lack of communication, 4% (2 individuals) of the patients voluntarily withdrew per medical advice since one individual was diagnosed with hypothyroidism and the other with colitis. Use of Precarb was not permitted at that time since those patients were in the initial stages of full medical care. Sixteen percent of the individuals are not evaluated as a whole due to their lack of adherence in this study; however, they are

receiving follow-up separately, are being evaluated and good results are being observed. Cholesterol levels, triglycerides, body mass index and waist-to-hip ratio decrease as a result, obtaining better health for the individuals, reducing their cardiac risk and chances of metabolic syndrome during the time of the study.

Introduction

These days, obesity and overweight are now so astonishingly common that they are of higher interest than infectious diseases which at their time marked patterns of medical conduct and national policies in several countries. Worldwide, there is a very high rate of obesity. In developed countries it represents a serious public health problem. It appears that its incidence is closely related to success, comfort and a sedentary lifestyle; however, developing countries also have high rates of prevalence since it is estimated that more than 50% of adult women are obese. Mexico is no exception. One cannot help but notice that Northern Mexico has the highest percentages of obesity, as it is estimated that more than 35% of all obese people in the country are located in that area.¹ So we also note that the highest concentration of obese people are between 40 and 60 years old.² And obesity induces type-2 diabetes, coronary disease, stroke, increases the chances of several types of cancer, gallbladder disease, musculoskeletal disorders and respiratory problems.³ They say that 26% of obese people suffer from hypertension and that 42% of them are diagnosed with colon cancer. Eighty percent of non-insulin dependent diabetics are obese and according to the American Medical Association, obese women have a 300% chance of developing a pulmonary embolism. Accordingly, it is clear that obesity is a health problem that should especially concern us and, therefore, this protocol is developed in order to provide one more tool to the population of this geographical area, especially where they are greatly influenced by the eating habits of our neighboring country, complete, reliable and safe help that favors weight loss without needing to completely abstain from the foods that largely form part of our gastronomic culture.

Description of product used in the study: PreCarb contains – Phaseolamin - Phase2™ a non-stimulant, standardized substance, clinically proven neutralizer of complex carbohydrates (starches). It is a natural product extracted from White Kidney Beans (*Phaseolus Vulgaris*).

Action Mechanism: CARBOHYDRATE DIGESTION

Mouth: Chewing grinds food, turning it into small particles that mix with saliva. In a pH alkaline environment, the enzyme (**alpha-amylase**) in saliva (ptyalin), which is secreted by the parotid gland, begins to hydrolyze/degrade the starch molecules into smaller molecules (dextrins and maltose). Stomach: Mechanical digestion takes place here through successive contractions (peristalsis) of muscle fibers located in the stomach wall. This action mixes particles of food with gastric secretions so that the chemical activity of digestion is carried out

effectively. Gastric acid (hydrochloric acid) secretions counteract/interrupt the alkaline activity of **alpha-amylase**. Finally, at the gastric level, chyme, a dense, creamy mass (semi-liquid), is formed, ready to pass to the duodenum (first part of the small intestine).

Small Intestine: In this digestive tract exocrine secretions from the pancreas are received (from the duodenum) and from the intestine. Pancreatic secretions (via the common bile duct) reach the duodenum. Pancreatic **alpha-amylase** continues degrading starch into maltose.

Intestinal juices (produced by intestinal secretions) contain three disaccharides (sucrose, lactose and maltose), which act on their respective disaccharides to turn them into monosaccharides (glucose, galactose and fructose) so that they are ready to be absorbed to the portal vein (entry to the portal vein of the blood via the liver). Once absorbed, all monosaccharides are converted into glucose. **If there is an excess for your immediate energy need, the glucose is converted into glycogen or fat.**

The mechanism of action of phaseolamin is very simple. The phaseolamin in Precarb neutralizes the digestive enzyme alpha-amylase and may temporarily reduce the caloric impact of foods high in complex carbohydrates by preventing a high percentage of them from being converted into glucose; thus, Precarb does not block simple sugars.

Independent Statistical Analyses

Of 100% of the individuals evaluated, 97% obtained positive results, reducing body weight. Thirty percent increased their physical activity 15 days after starting the study. The same percentage made modifications in their eating habits. Sixteen percent of them reduced their body mass index to the extent that they moved from being obese to the classification of overweight.

Ten percent of the individuals got out of the cardiac risk index in only one month by reducing their waist-to-hip ratio. Twenty-five percent who had out of range cholesterol returned to normal numbers and 60% of patients who had out of range triglycerides returned to the normal range.

Independent Statistical Analysis. After the study was completed and the above manuscript published, Pharmachem, Inc. requested that we conduct an independent analysis of the raw data. We were able to obtain data from 49 of the 50 subjects and conducted two analyses: (1) a “per-protocol” analysis in which we excluded all data from the drop-outs and used only the data from the 37-39 subjects who had both beginning and ending test scores; and (2) an “intention to treat” analysis that is often requested by the FDA. This analysis involves including the data from the 11-12 dropouts by using the baseline measurements as their “last known measurement” and “carrying forward” these measurements as their ending measurements. For example, if a subject’s weight was 125.2 lbs at baseline, the same weight is used as though it was their ending weight thus showing that there was no change in weight during the study. In spite

of the fact that the FDA often requests this type of analysis, it is often criticized since it used data that was not actually obtained, but rather was artificially created for statistical purposes. A recent thoughtful analysis of this issue is available in a commentary in the reference¹ cited below.

Actual changes.

Table 1. Natrol Pre-Carb Study (16 February 2009)
Paired T-tests on Within-Subject Changes

Characteristic	N	Change ¹	
		Mean (Standard Deviation)	p-value
Weight	37	-2.34 (2.21)	<0.001
Waist to hip	39	-2.77 (2.55)	<0.001
Cholesterol	37	-8.92 (20.8)	0.01
Triglycerides	37	-20.16 (70.62)	0.09

1. Final value minus initial value

Table 2. Natrol Pre-Carb Study (16 February 2009)
Paired T-tests on Within-Subject Changes Using Intention to Treat Analysis

Characteristic	N	Change ¹	
		Mean (Standard Deviation)	p-value
Weight	49	-1.7 (2.2)	<0.001
Waist to hip	49	-2.2 (2.6)	<0.001
Cholesterol	49	-6.9 (18.3)	0.01
Triglyceride	48	-19.7 (64.2)	0.03

1. Final value minus initial value

It is our conclusion that based on the data provided to us, there were statistically significant changes during this 30-day study as shown in Tables 1 & 2 above.

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1. Feinman RD. Intention-to-treat: What is the question? *Nutrition & Metabolism*. 2009, 6.1. <http://www.nutritionandmetabolism.com/content/6/1/1>