The Anti-obesity Effect and the Safety of Taking "Phaseolamin™ 1600 diet"

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Beginning:

Obesity is said to be linked to life-style-related diseases such as diabetes, high blood pressure and hyperlipemia. Maintaining proper weight is important for both men and women, especially for women who would like to sustain a positive self image.

Obesity is defined as follows: Obesity does not simply mean that there is too much weight, it means that either the number of fat cells increase or the fat cells swell; both are states where the fat has accumulated excessively in the human body.

Research demonstrates that body fat measured in a CT scan has strong correlation with occurrence frequency of complications such as the myocardial blockage. The higher the body fat quantity, the higher occurrence frequency of complications.

In order to provide an accurate assessment of whether a person is obese or not, we should use CT scan to measure the body fat quantity; however, quite easily and accurately, we can often use "weight per height", which is also expressed as Body Mass Index (BMI), to measure the degree of obesity.

BMI is a Physique Index, which is calculated as Weight (kg) / height (m) / height (m). This index is the standard of WHO (World Health Organization); however, the Japanese Obesity Academic Society revised this criterion of Obesity due to the body type of Japanese people in 1999.

The new standard specifies that if one's BMI is higher than 25, then he/she is obese. Based on this standard, among Japanese males who are 30 years old or older, 30% of the population will be categorized as obese. Among Japanese females who are 60 years or older, also 30% of the population will be categorized as obese. However, BMI is not a perfect Index for the degree of obesity; the diameter around the waist should also be considered.

If a person who has sufficient insulin secretion consumes more energy through caloric intake than he/she exerts, then it becomes "an energy excessive state", and the surplus energy will be converted to fat and he/she eventually will become fat. When the inherited obesity element, eating habits and lack of exercise come together it advances to a state where it is diagnosed as obesity.

Aerobic exercise alone does not burn much body fat, therefore, the principle of obesity remedy and diet will be "the meal as primary and the exercise is secondary," and desirable diet foods are low energy balanced food. The low Carb weight loss method, which limits the intake of carbohydrates, maintains Lean Body Mass (LBM), increases basal metabolism, and is considered an efficient weight Loss method. From this point of view, Metabolic, Inc. developed "Phaseolamin™ 1600 Diet".

Phaseolamin is an extract from Phaseolus Vulgaris. Since it is an alpha-amylase inhibitor, it blocks part of the digestion of starch and delays the absorption of sugar from the intestinal tract.

Layer, Boivin et al. requested subjects to intake Phaseolamin with starch, and it is reported that the increase of blood glucose was restrained and secretion of insulin was decreased.

In the formula of "Phaseolamin™ 1600 diet", besides the main constituent Phaseolamin, it contains Clove, a seasoning that increases body temperature. In addition, it contains amino acids, such as Lysine, Arginine and Alanine.

This time, we have conducted an open test, which requested the minor obese examinees to take "Phaseolamin™ 1600 diet" for 8 weeks. Hence our test report follows:

I)Test Method:

1) **Test food:**
   The testing food is Metabolic, Inc.'s "Phaseolamin™ 1600 Diet" (We call it "Test Food" below). The main ingredients and their contents are indicated in Table 1, and its' nutritional facts are indicated in Table 2.

2) **Subjects:**
   We selected 10 subjects from the individuals who fulfilled the selection criteria, did not meet the elimination criteria and were willing to take this test food. Furthermore, in accordance with the principle of the Helsinki declaration we explained the test contents and methods before starting the test and obtained an agreement their formal agreement in written form.

   <Selection Criteria>
   1. Healthy adults between the ages of 20 and 55 years
   2. Body fat ratio is more than 25% for male and 30% for female
   3. BMI is between 23 and 30

   <Elimination Criteria>
   1. Individuals on medication which may affect the test results or those individuals already on a health food diet.
   2. Individuals who are pregnant or likely to be pregnant and who are lactating.

3. Individuals that excessively consume alcohol.
4. Individuals who have allergies.
5. Individuals who have a history of serious hepatopathy, renal damage and myocardial infractions.
6. Individuals with questionable health.

3) Test Period, design and intake method:

An open test is prepared and the subjects begin taking the test food from October 7th, 2004 until December 9th, 2004, totaling 8 weeks. There are three observation days: 1- before the intake of the test food 2- 4 weeks after continuous intake of the test food 3- 8 weeks after intake of the test food. Subjects take test food twice per day and each time take 3 capsules. Subjects take the test food 30 minutes before lunch and dinner, with either cold water or lukewarm water, without chewing on the test food. During the test period, subjects eat normal meals and exercise as per their usual daily routines.

4) Survey Items:

Before the test, 4 weeks after the start date, and 8 weeks after the start date, administrator measures the **Body Measurements** (height, weight, muscular mass, body fat ratio, body fat, abdomen fat ratio, BMI, Basal metabolism and Basal metabolism per weight (kg)), **Waist & Hip Measurements** (waist, hip, waist/hip ratio), **Blood Pressure**, **Drawn Blood** for blood inspection, **Subjective symptoms**, **Questions on their regular meals, and Caloric intake is checked.**

In biochemical examination of blood, end points include cholesterol, triglycerides, HDL-cholesterol , LDL- cholesterol, blood glucose levels, total protein, gross Albumen/Globulin ratio, Albumen (ALB), GOT, Alkaline phosphatase (ALP), lactate dehydrogenase (LDH), GPT, ?-GTP, Urea nitrogen, uric acid, creatinine, Na, K, Ca, Cl, Mg, P and serum iron.

In hematologic examination, white blood cell count, red blood cell count, hemoglobin, hematocrit, platelet count, mean corpuscular volume, mean red corpuscle Hemoglobin Concentration, and the total bilirubin were checked.

Regarding safety, it is judged comprehensively, based on subjective symptoms, observatory items and blood test results.

Table 1

Test Food Main Ingredients and Content

Main Ingredients	Contents (mg)
Phaseolamin	750
Clove	200
Lysine	20
Arginine	20
Alanine	20

Per 6 capsules (1.5 gr)

Table 2

Test Food Nutritional Facts

Energy	5.5kcal
Protein	0.28g
Fat	0.07g
Carbohydrates	0.95g
Na	20.7mg

Per 6 capsules (1.5 gr)

Table 3

Subjects Background

Number	10
Male	5
Female	5
Age	44.1 $\pm$ 8.4
Height	167 $\pm$ 8
Weight	74.5 $\pm$ 7.3

mean $\pm$ standard deviation

5) Statistical Processing:

Each measured value is indicated by mean value $\pm$ standard deviation, and the figure is indicated by a standard error of the mean (SEM). The Multiple Comparison for each measured value at the time prior to taking the test food, 4 weeks after intake and 8 weeks after intake are performed by the Dunnett Test, and subjective symptoms are measured by Wilcoxon Signed-Rank Test, and then modified by Bonferroni's Inequality. The significant level for each of the tests is specified as less than 5% using Two-Tail Tests. This test used Dr. SPSS II (SPSS Inc.) as its' statistical analysis software.

II) Test Result:

1. Subjects

Total ten subjects (5 male, 5 female), average age is 44.1± 8.4 years. The background information of all subjects is listed in Table 3.

2. Body measurement changes

The body measurement value changes are indicated in Table 4 and Figure 1. Regarding body weight, in comparison with the weight of 74.5±7.3 kg before taking the test food, the weight after taking the test food for 8 weeks was 72.7± 7.8 kg. The P value of the body weight reduction is 0.002, which reached the significant level.

Regarding body fat ratio, before taking the test food, it was 32.0±6.2%, after taking the test food for 4 weeks, it was 31.4±6.7%, P=0.011, and after 8 weeks, it was 30.8±6.6%, P<0.001, which means the reduction reached the significant level.

Regarding body fat, before taking the test food, it was 23.8±4.7kg, after taking the test food for 4 weeks, it was 23.1±5.3kg, P=0.028, and after 8 weeks, it was 22.4±5.1kg, P<0.001, which means the reduction volume reached the significant level.

Regarding Abdomen fat ratio, before taking the test food, it was 91.7±3.5%, and after 8 weeks, it was 90.7±3.9%, P=0.004, which means the reduction reached the significant level.

Regarding BMI, before taking the test food, it was 26.6±1.7, and after 8 weeks, it was 25.9±1.8, P=0.002, which means the reduction reached the significant level.

Regarding Basal metabolism quantity per weight (kg), before taking the test food, it was 18.7±1.8kcal/kg·d, after taking the test food for 4 weeks, it was 18.8±1.9kcal/kg·d, P=0.024, and after 8 weeks, it was 19.0±1.9 kcal/kg·d, P<0.001, which means the increases in quantity reached the significant level.

Regarding the Muscular quantity and the Basal metabolism quantity, there is no significant change encountered before taking the test food, 4 weeks later, and 8 weeks later.

3. Waist·Hip circumference changes

The change of Waist·Hip circumference is indicated in Table 5 and Figure 2.

Regarding the waist circumference change, before taking the test food, it was 96.6±4.0cm, and after taking for 8 weeks, it was 91.8±4.3cm, P<0.001. The reduction reached a significant level.
Regarding the hip circumference change, before taking the test food, it was 103.3±5.3cm, and after taking for 4 weeks, it was 102.1±4.9cm, P=0.010, and

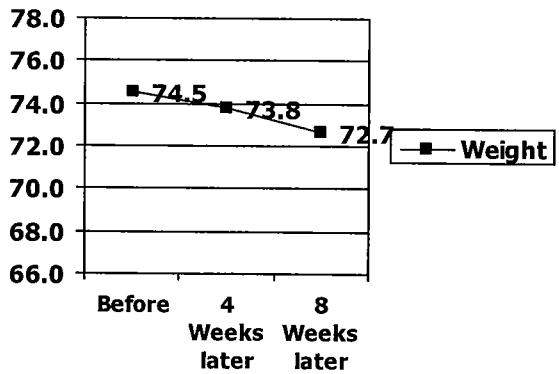
after taking for 8 weeks it was 100.2±5.4cm, P<0.001. The reduction reached the significant level.

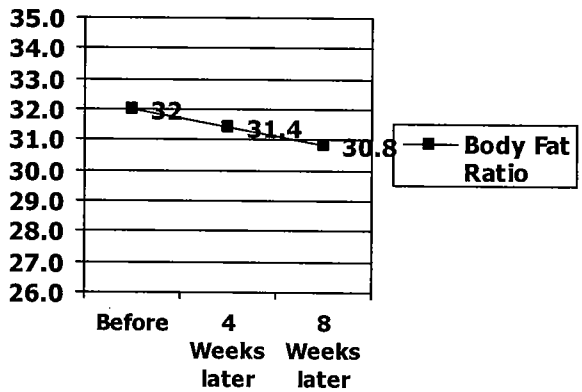
Regarding Waist/Hip Ratio, there was no significant difference encountered before taking the test food, 4 weeks later and 8 weeks later.

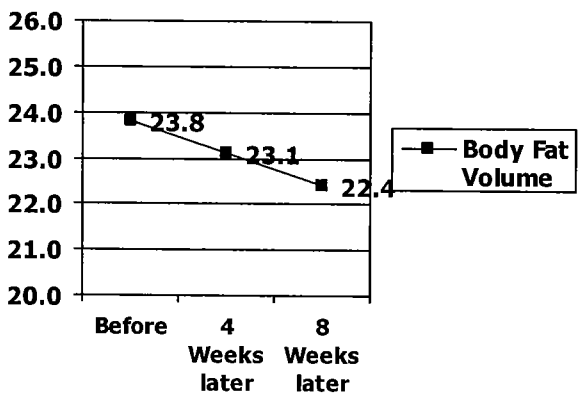
Table 4 Body Measurement Changes

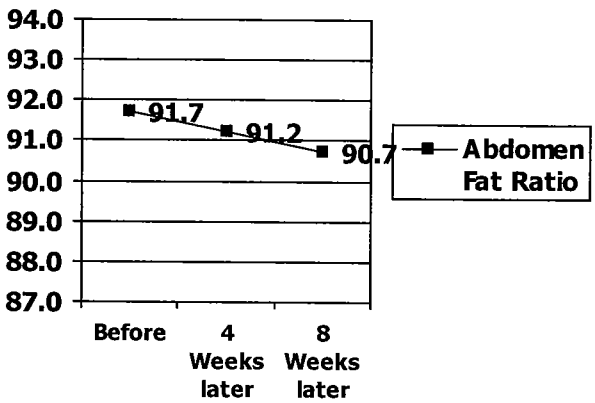
Test Item	Unit	Before	4 weeks later		8 weeks later	
Weight	kg	74.5±7.3	73.8±7.8	*P*=0.273	72.7±7.8	*P*=0.002**
Muscular Volume	kg	47.9±7.2	47.9±7.3	*P*=0.996	47.6±7.3	*P*=0.330
Body fat ratio	%	32.0±6.2	31.4±6.7	*P*=0.011*	30.8±6.6	*P*=<0.001***
Body fat volume	kg	23.8±4.7	23.1±5.3	*P*=0.028*	22.4±5.1	*P*=<0.001***
Abdomen fat ratio	%	91.7±3.5	91.2±3.8	*P*=0.156	90.7±3.9	*P*=0.004**
BMI		26.6±1.7	26.3±1.9	*P*=0.309	25.9±1.8	*P*=0.002**
Basal metabolism quantity	Kcal	1391±204	1391±210	*P*=1.000	1385±212	*P*=0.423
Basal (metabolism quantity)/weight (kg)	Kcal/kg·d	18.7±1.8	18.8±1.9	*P*=0.024*	19.0±1.9	*P*<0.001***

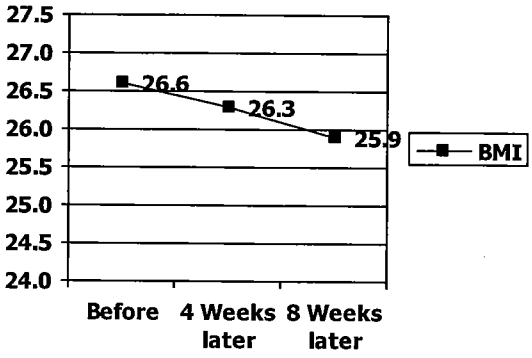
mean ± standard deviation (n=10) compare with before taking test food
*:*P*<0.05 **:*P*<0.01 ***: *P*<0.001











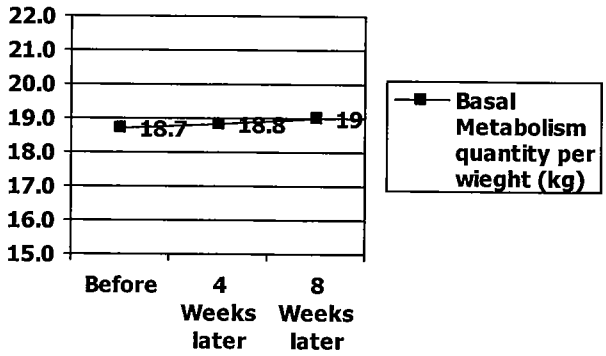
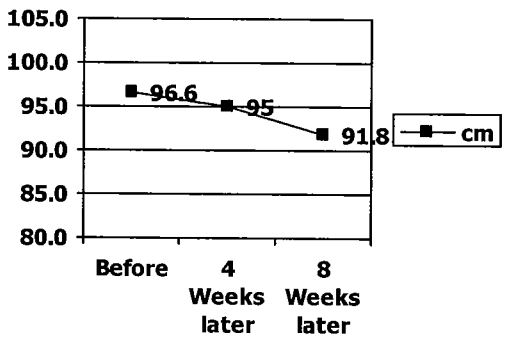


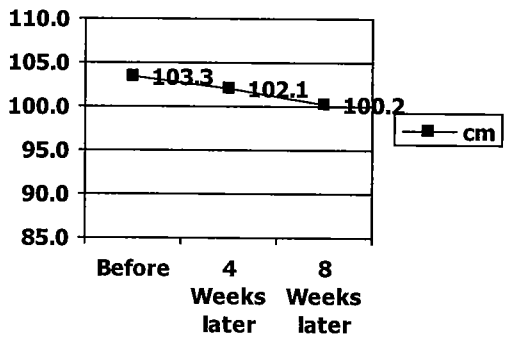
Table 5 Waist/Hip Changes

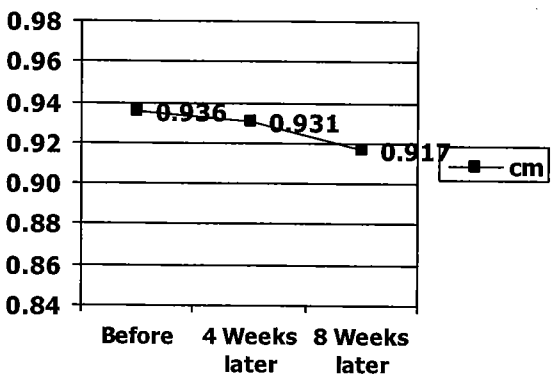
Test Item	Unit	Before	4 weeks later		8 weeks later	
Waist	cm	96.6± 4.5	95.0± 4.7	*P*=0.133	91.8± 4.3	*P*<0.001***
Hip	cm	103.3± 5.3	102.1± 4.9	*P*=0.010*	100.2± 5.4	*P*<0.001***
Waist/Hip ratio		0.936±0.027	0.931±0.031	*P*=0.858	0.917± 0.026	*P*=0.091

mean ± standard deviation compare with before taking test food (n=10)
*:*P*<0.05 ***: *P*<0.001

WAIST/HIP SIZE CHANGES







(n=10)
*:*P*<0.05 ***: *P*<0.001

4. Blood pressure change

The change of blood pressure is indicated in Table 6.

Regarding the systolic blood pressure, before taking the test food, it was 122±16mmHg, and 4 weeks later, it was 116±10mmHg, P=0.047, and 8 weeks later it was 113±11mmHg, P=0.010. The reduction reached the significant level.

Regarding the diastolic blood pressure, before taking the test food, it was 80±11mmHg, and 4 weeks later, it was 74±9mmHg, P=0.003, and 8 weeks later it was 69±8mmHg, P<0.001. The reduction reached the significant level.

Table 6 Blood Pressure Change

Test Item	Unit	Before	4 weeks later		8 weeks later	
Systolic blood pressure	mmMg	122± 16	116± 10	*P*=0.047*	113± 11	*P*=0.010**
Diastolic blood pressure	mmHg	80±11	74±9	*P*=0.003**	0.917± 0.026	*P*<0.001***

mean ± standard deviation (n=10)
compare with before taking test food
*:*P*<0.05 **:*P*<0.01 ***: *P*<0.001

5. Blood Test value change

Blood test value change is indicated in Table 7.

Regarding triglycerides, before taking the test food, it was 123±49mg/dL, and after taking the test food for 4 weeks, it was 90±27mg/dL, P=0.041, and after taking the test food for 8 weeks, it was 86±22mg/dL, P=0.019. The reduction reached the significant level.

Regarding HDL·cholesterol, before taking the test food, it was 58.2±10.3mg/dL, and after taking the test food for 4 weeks, it was 52.1±9.4mg/dL, P<0.001, and after taking the test food for 8 weeks, it was 53.4±9.7mg/dL, P=0.001. The reduction reached the significant level.

Regarding GPT, before taking the test food, it was 33.0±16.5 IU/L/37°C, and after taking the test food for 4 weeks, it was 27.6±13.8 IU/L/37°C, P=0.036. The reduction reached the significant level.

Regarding Cl, before taking the test food, it was 102±2mEq/L, and after taking the test food for 4 weeks, it was 103±2mEq/L, P=0.040. The increase reached the significant level.

Regarding Mg, before taking the test food, it was 2.35±0.16mg/dL, and after taking the test food for 8 weeks, it was 2.23±0.09mg/dL, P=0.036. The reduction reached the significant level.

Regarding Blood platelet count, before taking the test food, it was $25.7\pm6.5X10^4/\mu L$, and after taking the test food for 8 weeks, it was $27.6\pm5.6X10^4/\mu L$, P=0.003. The increase reached the significant level.

Regarding Average red corpuscle Hemoglobin Concentration, before taking the test food, it was 33.2±0.9%, and after taking the test food for 8 weeks, it was 32.6±1.5%, P=0.023. The reduction reached the significant level.

Regarding the other items, none of them reached the statistically significant level.

Table 7 Blood Inspection Value Change

Blood Inspection Item	Unit	Standard Value	Before
Total Cholesterol	mg/dL	150-219	216±31
Triglycerides	mg/dL	50-149	123±49
HDL Cholesterol	mg/dL	M:40-86, P: 40-96	58.2±10.3
LDL Cholesterol	mg/dL	70-139	138±26
Blood glucose	mg/dL	70-109	90.7±12.5
Total Protein	g/dL	6.7-8.3	7.79±0.27
Albumen/Globulin ratio		1.2-2.0	1.43±0.18
Albumen (ALB)	g/dL	4.0-5.0	4.56±0.19
GOT	IU/L/37°C	10-40	24.2±8.6
Alkaline phosphatase (ALP)	IU/L/37°C	115-359	226±69
Lactate Dehydrogenase	IU/L/37°C	115-245	191±28
(LDH)	IU/L/37°C	5-40	33.0±16.5
GPT	IU/L/37°C	M:70, F:30	31.3±14.5
y. GTP	mg/dL	6.0-20.0	13.9±3.3
Urea nitrogen	mg/dL	M: 3.7-7.0. F:2.5-7.0	5.54±0.89
Uric acid	mg/dL	M: 0.61-1.04, F:0.47 -	0.73±0.11
Creatine	mEq/L	0.79	141±1
Na	mEq/L	136-147	4.03±0.36
K	mg/dL	3.6-5.0	9.46±0.28
Ca	mEq/L	8.7-10.1	102±2
CI	mg/dL	98-109	2.35±0.16
Mg	mg/dL	1.8-2.6	3.39±0.58
P	μg/dL	2.4-4.3	85.4±38.4
Serum Iron	/μL	M:54-200. F:48-154	7210±1575
White Blood Cell Count	x 10^4/μL	M:3900-9800, F3500-	474±41
Red Blood Cell Count	g/dL	9100	14.3±1.8
Hemoglobin	%	M:427-570, F:376-500	43.1±4.5
Hematocrit	x 10^4/μL	M:13.5-17.6. F:11.3-15.2	25.7±6.5
Blood Platelet	fL	M:39.8-51.8. F:33.4-44.9	90.8±4.0
Mean Corpuscular Volume	%	M:13.1-36.2. F13.0-36.9	33.2±0.9
Mean Corpuscular Hemoglobin Concentration		M82.7-101.6. F:30.7-36.6	30.1±1.9
Mean Corpuscular Hemoglobintotal	pg	M:31.6-36.6. F:30.7-36.6	0.42±0.25
Bilibrubin		M:28.0-34.6. F:26.3-34.3	
	mg/dL	0.2-1.0	

Blood Inspection Item	Unit	Standard Value	4 Weeks	Later	8 weeks later	
Total Cholesterol	mg/dL	150-219	209±44	*P*=0.548	205±40	*P*=0.239
Triglycirides	mg/dL	50-149	90±27	*P*=0.041*	86±22	*P*=0.019*
HDL Cholesterol	mg/dL	M:40-86, P: 40-96	52.1±9.4	*P*<0.001***	53.4±9.7	*P*=0.001***
LDL Cholesterol	mg/dL	70-139	142±46	*P*=0.797	137±39	*P*=0.978
Blood glucose	mg/dL	70-109	94.7±12.2	*P*=0.183	93.7±8.9	*P*=0.356
Total Protein	g/dL	6.7-8.3	7.78±0.21	*P*=0.990	7.69±0.33	*P*=0.430
Albumen/Globulin ratio		1.2-2.0	1.48±0.23	*P*=0.250	1.47±0.24	*P*=0.391
Albumen (ALB)	g/dL	4.0-5.0	4.61±0.21	*P*=0.578	4.54±0.26	*P*=0.910
GOT	IU/L/37°C	10-40	24.0±11.8	*P*=0.0983	22.7±7.51	*P*=0.420
Alkaline phosphatase (ALP)	IU/L/37°C	115-359	222±80	*P*=0.0830	211±74.3	*P*=0.100
Lactate Dehydrogenase (LDH)	IU/L/37°C	115-245	190±33	*P*=0.0935	199±22.1	*P*=0.139
GPT	IU/L/37°C	5-40	31.3±19.1	*P*=0.0638	27.6±13.8	*P*=0.036*
y. GTP	mg/dL	M:70, F:30	27.5±13.3	*P*=0.157	28.6±15.8	*P*=0.358
Urea nitrogen	mg/dL	6.0-20.0	14.2±4.1	*P*=0.962	12.1±2.7	*P*=0.195
Uric acid	mg/dL	M: 3.7-7.0. F:2.5-7.0	5.53±0.88	*P*=0.996	5.44±0.91	*P*=0.682
Creatine	mEq/L	M: 0.61-1.04, F:0.47 -0.79	0.72±0.11	*P*=0.740	0.76±0.17	*P*=0.130
Na	mEq/L	136-147	141±2	*P*=0.531	141±1	*P*=0.414
K	mg/dL	3.6-5.0	3.98±0.24	*P*=0.808	4.05±0.38	*P*=0.965
Ca	mEq/L	8.7-10.1	9.49±0.25	*P*=0.945	9.33±0.29	*P*=0.393
CI	mg/dL	98-109	103±2	*P*=0.040*	102±2	*P*=0.973
Mg	mg/dL	1.8-2.6	2.26±0.08	*P*=0.123	2.23±0.09	*P*=0.036*
P	μg/dL	2.4-4.3	3.28±0.27	*P*=0.683	3.33±0.45	*P*=0.888
Serum Iron	/μL	M:54-200. F:48-154	97.2±46.5	*P*=0.565	93.6±34.9	*P*=0.750
White Blood Cell Count	x 10^4/μL	M:3900-9800, F3500-9100	6880±1783	*P*=0.637	6870±1439	*P*=0.621
Red Blood Cell Count	g/dL		466±49	*P*=0.369	467±48	*P*=0.462
Hemoglobin	%	M:427-570, F:376-500	14.0±2.2	*P*=0.509	13.9±2.5	*P*=0.215
Hematocrit	x 10^4/μL	M:13.5-17.6. F:11.3-15.2	42.5±5.6	*P*=0.685	42.3±6.2	*P*=0.579
Blood Platelet	fL	M:39.8-51.8. F:33.4-44.9	26.7±6.6	*P*=0.121	27.6±5.6	*P*=0.003*
Mean Corpuscular Volume	%	M:13.1-36.2. F13.0-36.9	91.0±5.6	*P*=0.940	90.3±7.1	*P*=0.808
Mean Corpuscular Hemoglobin concentration	pg	M82.7-101.6. F:30.7-36.6	33.0±1.2	*P*=0.509	32.6±1.5	*P*=0.023*
Mean Corpuscular HemoglobinTotal		M:28.0-34.6. F:26.3-34.3	30.0±2.5	*P*=0.968	29.5±3.1	*P*=0.148
Bilibrubin	mg/dL	0.2-1.0	0.57±0.24	*P*=0.059	0.57±0.24	*P*=0.059

mean ± standard deviation (n=10)
compare with before taking test food
*:*P*<0.05 **:*P*<0.01 ***: *P*<0.001

6. Calorie Intake change

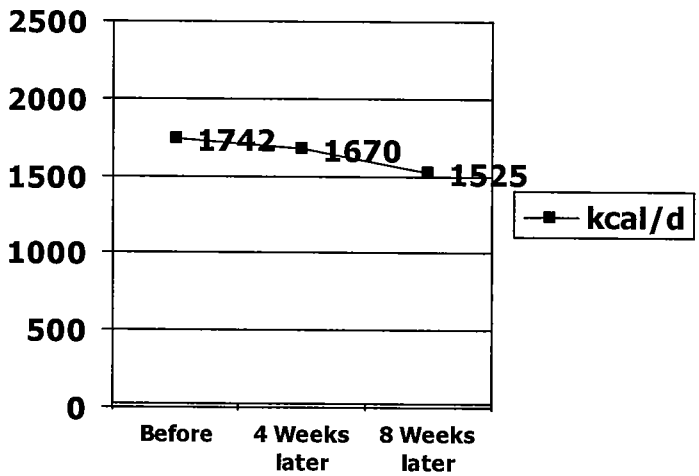
Intake energy amount change is indicated in Table 8, and Figure 3. Regarding the intake energy amount, it was 1742±265kcal/d, and after intaking the test food for 8 weeks, it was 1525±249kcal/d, P=0.010. The reduction reached the significant level

Table 8- Calorie Intake Change

Test Item	Unit	Before	4 weeks later		8 weeks later	
Intake energy amount	Kcal/d	1742± 254	1670± 278	*P*=0.485	1525± 249	*P*=0.010*

mean ± standard deviation (n=10)
compare with before taking test food
*:*P*<0.05

Figure 3 – Intake Energy Amount Change



mean ± standard deviation (n=10)
compare with before taking test food
*:*P*<0.05

7. Subjective symptom change

The change of subjective symptoms is indicated in Table 9.

Regarding Subjective symptoms, there are no significant differences encountered before taking the test food, 4 weeks later and 8 weeks later.

Table 9

Symptoms	Before	4 weeks later		8 weeks later	
Irritation	3.80± 0.42	3.90± 0.32	*P*=0.317	4.00± 0.00	*P*=0.157
Hypobulia	3.70± 0.48	3.70± 0.67	*P*=1.000	3.90± 0.32	*P*=0.317
Anorexia	4.00± 0.00	4.00± 0.00	*P*=1.000	3.90± 0.32	*P*=0.317
Feeling of weariness	3.90± 0.32	3.80± 0.42	*P*=0.564	3.80± 0.42	*P*=0.317
Insomnia	4.00± 0.00	3.90± 0.32	*P*=0.317	3.90± 0.32	*P*=0.317
Headache	3.70± 0.48	3.50± 0.53	*P*=0.157	3.70± 0.48	*P*=1.000
Ear Buzzing	4.00± 0.00	3.90± 0.32	*P*=0.317	4.00± 0.00	*P*=1.000
Vertigo	4.00± 0.00	4.00± 0.00	*P*=1.000	4.00± 0.00	*P*=1.000
Itchiness (rash)	4.00± 0.00	3.90± 0.32	*P*=0.317	4.00± 0.00	*P*=1.000
Vomiting	4.00± 0.00	4.00± 0.00	*P*=1.000	4.00± 0.00	*P*=1.000
Diarrhea	3.90± 0.32	4.00± 0.00	*P*=0.317	4.00± 0.00	*P*=0.317
Loose Stool	3.70± 0.48	3.70± 0.48	*P*=1.000	3.50± 0.71	*P*=0.414
Constipation	3.70± 0.48	3.80± 0.42	*P*=0.317	3.90± 0.32	*P*=0.157
Bloated	3.70± 0.48	3.70± 0.48	*P*=1.000	3.90± 0.32	*P*=0.157
Stomach ache	4.00± 0.00	4.00± 0.00	*P*=1.000	3.90± 0.32	*P*=0.317

mean ± standard deviation (n=10)
P value is obtained by comparing with before taking test food
Survey Answers: 1. Strongly 2. Yes 4. Slightly 4. No

8. Safety

During the test period, for blood examination items, blood pressure, subjective symptoms etc., there is no phenomenon that can be considered to be a problem.

III) Considerations:

In order to check the efficacy and the safety of "Phaseolamin™ 1600 Diet," we chose 10 subjects who met the requirements below to conduct the open test. Dosage: Three capsules taken twice a day. The subjects took the test food for 8 weeks.

1) Between 20 and 55 years of age
2) For men, the body fat ratio is higher than 25%, and for women, the body fat ratio is higher than 30%
3) BMI is between 23 and 30

In comparison to previous values before taking the test food, the changes of their weight, body fat ratio, body fat volume, abdomen fat ratio, BMI, basal metabolic quantity per weight (kg), waist size, hip size have reached statistical significant levels. The possible reason for the increase of the basal metabolic quantity per weight (kg) is that during the period, the intake of meals and amino acids (lysine, arginine and alanine) help to maintain LBM. Regarding blood pressure, both systolic and diastolic blood pressure are reduced statistically significant. Compared with the values before the subjects took test food, Triglycerides, HDL-cholesterol, GPT, Cl, Mg, blood platelet number, and the average red corpuscle hemoglobin concentration, showed significant changes statistically, all of them were within the range of standard value changes.

Compared with the values before taking the test food, statistically triglycerides were reduced significantly after 4 weeks and 8 weeks. The reduction of Triglycerides in serum means the increase of fat metabolism and is considered that the intake of the test food possibly inhibited the absorption of starch and excessive accumulation of fat was reduced in the fat cells.

Generally, if we keep blood glucose within normal ranges individuals are not likely to feel hungry. The blood glucose of subjects was stable throughout the test period; however the caloric intake 8 weeks after, compared with the value before the subjects took the test food, the reduction reached a statistically significant level.

Ballerini [6] chose 60 healthy people, who were 5 to 15 kgs over weight for his test. One group took Phaseolamin (500mg), and the other group took placebo. One capsule before each meal. The test period was 30 days. The results indicated that the Phaseolamin group reduced body weight by 4.0%, while the placebo reduced the body weight by 0.5% and Phaseolamin group reduced body fat volume by

10.5%, while placebo group was reduced by 1.3%. Phaseolamin group reduced their waist size by 3.4%, while placebo group reduced by 0.5%. Phaseolamin group reduced their hip size by 1.4%, while placebo group reduced by 0.1%.

Similar results were obtained in this test. In comparison with the value before subjects took the test food and 8 weeks later, there was a 2.4% weight reduction, 5.9% body fat volume reduction, 5.2% waist size reduction and 2.9% hip size reduction. The efficacy of the test food was clear.

Also, from subjective symptoms and observation, there were no adverse effects caused by the test food ingested during the test food intake period.

Based on the above results, this test food (Phaseolamin™ 1600 Diet) is considered to be a safe and effective weight loss supplement.

IV) Summary:

In order to check the safety and the weight loss efficacy of (Phaseolamin™ 1600 Diet), we have conducted this open test. This test collected 10 subjects whose body fat ratios for men were above 25%, for women were above 30% and BMI index between 23 and 30. The subjects were requested to take "Phaseolamin™ 1600 diet" for 8 weeks.

By taking the test food, the reduction of body weight, body fat ratio, body fat, abdomen fat ratio, BMI, waist-hip size and Triglycerides in the blood serum reached statistically significant levels and increased the basal metabolism quantity per weight (kg) which also reached the significant level. Furthermore, from subjective symptom and observation, no clinical abnormality was found. Therefore, this test food (Phaseolamin™ 1600 Diet) is considered a safe and effective weight loss supplement.

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