The Osteoporosis Education Project

A Division of Leading Edge Research, Inc.
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Working with nature to regenerate bone health

Pilot Clinical Study Assessing the Impact on Bone Resorption and Bone Mineral Density Of the Dietary Supplement Cal-Vantage™

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Introduction

In February 2003 The Osteoporosis Education Project began a pilot clinical study assessing the impact of Cal-Vantage™ on bone resorption, weight and blood pressure. The findings of this clinical study were reported in December of 2003.

At that time, December of 2003, it was decided to extend this initial short-term study to a full year pilot study looking at the impact of Cal-Vantage™ on bone mineral density. In this document we report the findings of that 12-month study. The original bone mineral density tests were collected during May and June of 2003. The 12 month follow-up bone density measurements were taken one year later.

The endpoints in this extension study were (1) bone mineral density, and (2) bone resorption as measured by urine NTx. All study subjects were postmenopausal women who were at least five years beyond their last menstrual period. Thirteen postmenopausal women participated in the original short-term study and 11 women continued on for the full year study. All subjects were consistent in their use of Cal-Vantage™ over the full study period.

Cal-Vantage™ is a new multivitamin/mineral and herbal dietary supplement designed to enhance bone health. Each subject was given six tablets of Cal-Vantage™ daily (3 with breakfast and 3 at bedtime).

Six tablets of Cal-Vantage™ contain the following nutrients:

1000 mg. of Calcium (from citrate, malate and carbonate)
500 mg. of Magnesium (from Oxide)
20 mg. of zinc (from monomethionine)
1.5 mg. of copper (from citrate)
1.5 mg. of boron (from amino acid chelate)
15 mg. of manganese (from amino acid chelate)
500 mg. of Vitamin C (from ascorbic acid)
400 IU of Vitamin D (cholecalciferol)

1 mg. of Vitamin K (phylloquinone)
50 mg. of Thiamin (Vitamin B-1 from mononitrate)
50 mg. of Pyridoxine HCL (Vitamin B-6)
800 mcg. of Folate
100 mcg. of cyanocobalamin (Vitamin B-12)
50 mg. of Horsetail Herb (Silica)
200 mg. of Coleus Forskohlii Extract (10% Forskolin)
500 mg. of Tumeric (Curcuma longa, 95% curcumin)
300 mg. of Fructooligosaccharides

Subjects

All subjects were women five years or more beyond their last period. Ages of the subjects are given below. All were in good health and exhibited no known cause of excessive bone loss.

Cal-Vantage	Age
PB	62
MFo	78
CG	54
JL	57
IM	75
JP	70
SR	53
JR	62
BS	55
MS	71
AS	71

Bone Mineral Density Changes at 12 Months

Table #1 below provides the data on spinal bone mineral density changes from baseline to 12 months. Of the eleven study subjects seven gained some degree of spinal bone density. Of these seven, four are considered statistically significant. Of the eleven study subjects four lost some degree of spinal bone density. Of those who lost spinal BMD, two are considered statistically significant. Five of the eleven study subjects had no significant change in spinal BMD.

Table 1

	Baseline AP Spine		52 Weeks AP Spine			
	g/cm^2	T Score	g/cm^2	T Score	% Change	Statistical Significance
PB	0.827	-3.10	0.813	-3.20	-1.69%	None
MFo	1.104	-0.80	1.241	0.30	**12.41%**	Sig. Inc.
CG	0.991	-1.70	0.992	-1.70	**0.10%**	None
JL	0.879	-2.70	0.835	-3.00	-5.01%	Sig. Dec.
IM	0.922	-2.30	0.885	-2.60	-4.01%	Sig. Dec.
JP	0.805	-3.30	0.842	-3.00	**4.60%**	Sig. Inc.
SR	0.920	-2.30	0.925	-2.30	**0.54%**	None
JR	0.838	-3.00	0.826	-3.10	-1.43%	None
BS	0.917	-2.40	0.956	-2.00	**4.25%**	Sig. Inc.
MS	0.811	-3.20	0.839	-3.00	**3.45%**	Sig. Inc.
AS	0.522	-4.51	0.535	-4.39	**2.49%**	None

	Positive Percent Change

Table # 2 provides the data on total hip bone density changes at 12 months. Of the eleven study subjects two gained some degree of total hip bone density. Of the eleven study subjects, nine lost some degree of total hip bone density. Of these decreases, three were statistically significant. Six of the eleven study subjects had no significant change in total hip BMD.

	Baseline Total Hip		52 Weeks Total Hip			
	g/cm^2	T Score	g/cm^2	T Score	% Change	Statistical Significance
PB	0.801	-1.70	0.827	-1.40	**3.25%**	Sig. Inc.
MFo	0.840	-1.30	0.804	-1.60	-4.29%	Sig. Dec.
CG	0.648	-2.28	0.616	-3.20	-4.94%	Sig. Dec.
JL	0.876	-1.00	0.854	-1.20	-2.51%	Sig. Dec.
IM	0.757	-2.00	0.742	-2.20	-1.98%	None
JP	0.765	-2.00	0.750	-2.10	-1.96%	None
SR	0.713	-2.40	0.702	-2.50	-1.54%	None
JR	0.804	-1.60	0.792	-1.90	-1.49%	None
BS	0.814	-1.60	0.811	-1.60	-0.37%	None
MS	0.616	-3.20	0.652	-2.90	**5.84%**	Sig. Inc.
AS	0.744	-1.62	0.731	-1.73	-1.75%	None

	Positive Percent Change

Table # 3 provides the data on neck hip bone density changes at 12 months. Of the eleven study subjects three gained some degree of neck hip bone density. Of the eleven study subjects, eight lost some degree of neck hip bone density. Of these decreases, two were statistically significant. Eight of the eleven study subjects had no significant change in total hip BMD.

	Baseline Neck		52 Weeks Neck			
	g/cm^2	T Score	g/cm^2	T Score	% Change	Statistical Significance
PB	0.799	-1.50	0.810	-1.40	**1.38%**	None
MFo	0.741	-2.00	0.722	-2.20	-2.56%	None
CG	0.604	-3.10	0.599	-3.20	-0.83%	None
JL	0.859	-1.00	0.815	-1.40	-5.12%	Sig. Dec.
IM	0.740	-2.00	0.730	-2.10	-1.35%	None
JP	0.762	-1.80	0.737	-2.00	-3.28%	Sig. Dec.
SR	0.701	-2.30	0.689	-2.40	-1.71%	None
JR	0.763	-1.80	0.753	-1.90	-1.31%	None
BS	0.775	-1.70	0.767	-1.80	-1.03%	None
MS	0.604	-3.10	0.640	-2.80	**5.96%**	Sig. Inc.
AS	0.604	-2.21	0.606	-2.19	**0.33%**	None

	Positive Percent Change

The attached Excel document provides the data sheet on individual study subject BMD changes.

Bone Resorption Changes at 12 Months

In this study bone resorption was measured using the Ostex NTx urine test. The manufacturer's recommended guidelines were followed for collection, transportation and processing of these samples.

Table # 4 provides the data on bone resorption changes at twelve months.

Table 4

	Baseline NTx Urine Score	52 Weeks NTx Urine Score	Percent Change Baseline to 52 Weeks
PB	**59**	**54**	**-8%**
Mfo	**59**	**34**	**-42%**
CG	**54**	**68**	**26%**
JC	**65**	**66**	**2%**
IM	**83**	**91**	**10%**
JP	**91.5**	**71**	**-22%**
SR	**62**	**62**	**0%**
JR	**62**	**75**	**21%**
BS	**100**	**44**	**-56%**
MS	**42**	**67**	**60%**
AS	**52**	**77**	**48%**
		Average Change	**3%**

Table 5 – Changes in Weight at 12 and 52 Weeks of Cal-Vantage Use

	Weight				
Name	Baseline	12 Week	52 Weeks	Weight Lost or Gained	% Change Baseline to 52 Weeks
PB	144.00	146.75	145.00	-1.00	0.69%
MFo	158.63	153.00	152.00	6.63	-4.18%
CG	137.00	136.00	135.00	2.00	-1.46%
JL	175.00	170.00	175.00	0.00	0.00%
IM	124.00	117.50	120.00	4.00	-3.23%
JP	158.00	157.00	150.00	8.00	-5.06%
SR	123.25	130.00	117.00	6.25	-5.07%
JR	150.00	153.00	148.00	2.00	-1.33%
BS	127.75	128.00	131.00	-3.25	2.54%
MS	128.00	126.00	135.00	-7.00	5.47%
AS	128.00	125.00	123.00	5.00	-3.91%
			Average Baseline to 52 Weeks	2.06	-1.41%

Table 6A – Changes in Systolic at 12 and 52 Weeks of Cal-Vantage Use

	Top Score - Systolic				
Name	Baseline	12 Weeks	52 Weeks	% Change Baseline to 12 Weeks	% Change from Baseline to 52 Weeks
PB	117.67	90	112.00	-23.51%	-4.82%
MFo	130	127.33	140.00	-2.05%	7.69%
CG	100	114	94.00	14.00%	-6.00%
JL	122	117	120.00	-4.10%	-1.64%
IM	162.67	152.67	142.00	-6.15%	-12.71%
JP	120.67	122.67	140.00	1.66%	16.02%
SR	112	114.33	98.00	2.08%	-12.50%
JR	119.33	116	120.00	-2.79%	0.56%
BS	107.33	118.5	116.00	10.40%	8.08%
MS	116	116	124.00	0.00%	6.90%
AS	120	119	125.00	-0.83%	4.17%
			Average % Change Baseline to 52 Weeks		0.52%

Table 6B – Changes in Diastolic at 12 and 52 Weeks of Cal-Vantage Use

	Bottom Score - Diastolic				
Name	Baseline	12 weeks	52 Weeks	% Change Baseline to 12 Weeks	% Change from Baseline to 52 Weeks
PB	78.67	70	78.00	-11.02%	-0.85%
MFo	75	73.33	70.00	-2.22%	-6.67%
CG	70	78	64.00	11.43%	-8.57%
JL	79.33	79	70.00	-0.42%	-11.76%
IM	74.67	72.67	74.00	-2.68%	-0.90%
JP	79.33	81.33	85.00	2.52%	7.15%
SR	70	78.67	70.00	12.38%	0.00%
JR	67.67	64.33	70.00	-4.93%	3.44%
BS	71.33	69	74.00	-3.27%	3.74%
MS	78	76	72.00	-2.56%	-7.69%
AS	77.33	75.5	78.00	-2.37%	0.87%
			Average % Change Baseline to 52 Weeks		-1.93%

Comments from study subjects on qualitative changes:

Fracture Events

During this 52 week study none of the study subjects experienced a fracture.