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Randomized Study of Oral Spray GF in Patients Between 35 to 85 Years of Age

Growth Factor (GF) Sublingual Spray



Phase II Clinical Trial

CLINICALLY PROVEN RESULTS

2000 ng/ml Plant-Based Polymer Matrix Oral Spray Growth Factor (GF)

(Synergy One)

Phase II Clinical Trial Study Highlights

OBJECTIVE of STUDY:

- a. Evaluate effectiveness of 2000 ng/ml plant-based polymer matrix oral spray GF
- b. Assess IGF-1, Triglyceride, HDL and LDL levels over 6 months
- c. Assess liver and kidney enzymes over 6 months

PROTOCOL OUTLINE:

- a. 6-month randomized, double blind, clinical study
- b. Sponsored by Dr. Robert Lawrence & Dr. Babak Parisaa, Bushard Medical Group, Los Angeles, CA
- c. 200 patients: 112 females, 88 males, 35 to 80 years of age, average to fair health
- d. No unusual dietary restrictions 3 months prior to test
- e. No active autoimmune, inflammatory or infectious disease 6 months prior to test

DOSAGE:

- 3 sprays in the morning (equaling 2000 ng of GF) within one hour of awakening
- 3 sprays in the evening immediately before retiring
- 7 days per week for 6 consecutive months

KEY FINDINGS:

IGF 1

Patients using the Synergy One GF Plant-Based Polymer Matrix Oral Spray showed significant increase in IGF 1 levels from baseline:

IGF 1 Testing (figures shown in ng/ml)

			Days a	fter Base	1	
Patients	Avg Age	Baseline	<u>30</u>	<u>60</u>	<u>180</u>	<u>% Change</u>
Female	51	114	150	176	232	+102
Male	48	135	176	210	284	+109

HDL Levels

Patients using the Synergy One GF Plant-Based Polymer Matrix Oral Spray showed significant increase in HDL levels from baseline:

HDL Levels (figures shown in mg/dl)

	Days after Baseline					
Patients	Avg Age	Baseline	30	60	<u>180</u>	% Change
Female	51	36	42	49	53	+47
Male	48	28	34	48	56	+93

LDL Levels

Patients using the Synergy One GF Plant-Based Polymer Matrix Oral Spray showed significant decrease in LDL levels from baseline:

Days after Baseline					1	
Patients	Avg Age	Baseline	30	60	<u>180</u>	% Change
Female	51	172	169	154	137	-20
Male	48	161	152	141	124	-23

LDL Levels (figures shown in mg/dl)

Triglycerides

Patients using the Synergy One GF Plant-Based Polymer Matrix Oral Spray showed significant decrease in triglycerides from baseline:

Triglycerides (figures shown in mg/dl)

			Days a	after Bas		
Patients	Avg Age	Baseline	30	60	<u>180</u>	<u>% Change</u>
Female	51	201	166	144	121	-40.
Male	48	182	152	133	119	-35

Liver & Kidney Enzymes

- Measured at baseline, 30, 60 and 180 days
- Both placebo and test group indicated normal values throughout testing period with no notable fluctuation
- PHT was also measured at each testing; remained normal in both placebo and test group at each measurement

Additional Notations

Patients receiving the GF showed notable increases in

- Mental stability
- Muscle accretion
- Weight reduction
- Higher energy
- Elevated libido
- Epidermis rejuvenation
- Reacquired hair color and density
- No adverse side affects were noted in either placebo or test groups
- 194 of the original 200 patients successfully completed the 6-month study

CONCLUSIONS

- Dosage of 2000 ng/ml of GF in a plant-based polymer matrix encapsulation is an effective method for promoting the rejuvenation of cellular tissues when used sublingually in an oral application
- Test group subjects showed significant improvements in serum levels of IGF 1 and HDL
- Test group subjects showed significant decreases in serum levels of LDL and triglycerides
- Test subjects showed no negative serum readings in liver or kidney enzymes
- Test subjects reported no negative side effects