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

Growth Hormone (GH) Sublingual Spray

Phase II Clinical Trial

This study is no longer recruiting patients.

Patients on Placebo incurred dramatically different results. After the final test period of 180 days, cholesterol and triglyceride levels showed insignificant changes.

Liver and Kidney enzymes (ALT, SGOT, SGPT) were measured at baseline, 30, 60 and 180 days. The placebo and test group both indicated normal values throughout the testing period with no notable fluctuation. Parathyroid Hormone (PTH) was also measured at each testing and remained normal in both the placebo and test group at each measurement.

Notations

Noted among patients receiving the GH were increase in mental stability, muscle accretion, weight reduction, higher energy, elevated libido, epidermis rejuvenation, and reacquired hair color and density. In all 200 patients, no adverse side effects were noted. Of the original 200 patients participating in the study, 194 participated successfully in the program, completing the 6-month study.

Conclusion

The study suggests that a dosage of 2000 ng/ml of GH 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. The study found that test group subjects showed significant improvements in their serum levels of IGF-1 and HDL as well as decreases in their serum levels of LDL and triglycerides. Furthermore, the test subjects showed no negative serum readings in liver or kidney enzymes and reported no negative side effects.

Summary of Study Results

		PLACEBO GROUP			STUDY GROUP		
	Baseline	30 Days	60 Days	180 Days	30 Days	60 Days	180 Days
IGF-1 Testing	Female 114 ng/ml Male 135 ng/ml	116 ng/ml 138 ng/ml	119 ng/ml 141 ng/ml	118 ng/ml 139 ng/ml	150 ng/ml 176 ng/ml	176 ng/ml 210 ng/ml	232 ng/ml 284 ng/ml
HDL Testing	Female 36 mg/dl Male 28 mg/dl	36 mg/dl 29 mg/dl	35 mg/dl 28 mg/dl	36 mg/dl 29 mg/dl	42 mg/dl 34 mg/dl	49 mg/dl 48 mg/dl	53 mg/dl 56 mg/dl
LDL Testing	Female 172 mg/dl Male 161 mg/dl	170 mg/dl 162 mg/dl	171 mg/dl 161 mg/dl	170 mg/dl 162 mg/dl	169 mg/dl 152 mg/dl	154 mg/dl 141 mg/dl	137 mg/dl 124 mg/dl
Triglycerides	Female 201 mg/dl Male 182 mg/dl	200 mg/dl 182 mg/dl	200 mg/dl 182 mg/dl	201 mg/dl 182 mg/dl	166 mg/dl 152 mg/dl	144 mg/dl 133 mg/dl	121 mg/dl 119 mg/dl
Parathyroid Hormone (PTH)	Female <200 Male <200	Normal Normal	Normal Normal	Normal Normal	Normal Normal	Normal Normal	Normal Normal
Liver/Kindey enzymes	Female 21 U/L Male 26 U/L	21 U/L 26 U/L	21 U/L 26 U/L	21 U/L 26 U/L	21 U/L 26 U/L	21 U/L 26 U/L	21 U/l 26 U/L
ALT (Alkaline Phosphatase)	Female 61 U/L Male 74 U/L	61 U/L 74 U/L	61 U/L 74 U/L	61 U/L 74 U/L	61 U/L 74 U/L	61 U/L 74 U/L	61 U/L 74 U/L
SGOT (Serum Glutamic Oxylate Transaminase)	Female 25 U/ml Male 28 U/ml	22 U/ml 28 U/ml	23 U/ml 26 U/ml	25 U/ml 24 U/ml	25 U/ml 28 U/ml	25 U/ml 28 U/ml	25 U/ml 28 U/ml
SGPT (Seurm Glutamic Pyruvate Transaminase)	Female 18 U/ml Male 20 U/ml	18 U/ml 20 U/ml	18 U/ml 20 U/ml	19 U/ml 20 U/ml	18 U/ml 20 U/ml	18 U/ml 20 U/ml	18 U/ml 20 U/ml

Abstract

This phase II study will evaluate the effectiveness of a 2000 ng/ml plant-based polymer matrix oral spray GH and its efficacy for cellular regeneration.

Purpose

OBJECTIVES:

1. Clinically evaluate an assisted six month study involving the administration of a plant-based polymer matrix oral spray GH delivery system.
2. Assess IGF-1, Triglyceride, HDL and LDL levels for patients 35 to 80 years of age from an individual's baseline to maximum applicable change over a period of 6 months.
3. Assess Liver and Kidney enzymes on all study participants to insure zero degradation in healthy organs during testing procedures.

Study Type: Clinical

Further Study Details:

PROTOCOL OUTLINE: This is a randomized, double-blind study. Prior to randomization, each patient must be subjected to a two-week wash-out period wherein no nutritional vitamins & supplements, alcohol, tobacco, are used. Patients will fast without exercise for eight hours prior to Serum tests, which will include IRB Study Protocols, IGF-1, HDL, LDL, Triglycerides, Liver enzymes, and Kidney enzymes. Patients are randomized to receive either placebo or Oral Spray GH sublingually every day, three sprays in the morning upon awakening and three sprays in the evening prior to bedtime for 6 months. Patients will undergo serum testing to establish individual baselines. Replicated testing periods are 30 days, 60 days and 180 days.

Projected Accrual:

A total of 200 patients will be accrued for this study. Random ages with the bulk above 50 years. 50/50 male and female with average to fair health.

Eligibility

Ages Eligible for Study: 35 Years to 80 years

PROTOCOL ENTRY CRITERIA:

Patient Characteristics

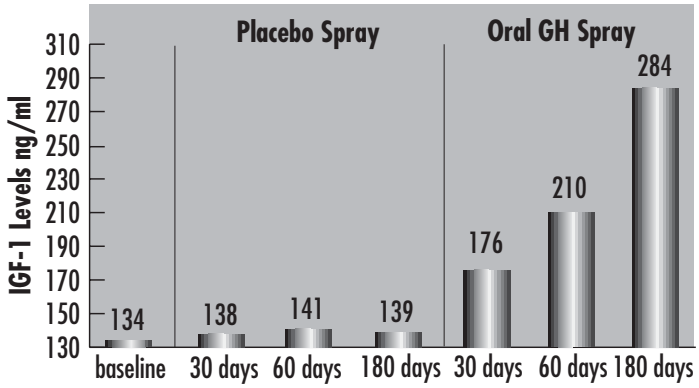
Reasonable health without progressive unintentional weight loss/gain more than 2.5% of the initial or ideal body weight and/or patient does not weigh less than 90% of ideal body weight. Biochemical parameters of nutrition defined by two or more of the following measurements over the past 3 months: Serum albumin no less than 3.7 g/dL; Serum transferrin concentration more than 200 mg/dL; Serum prealbumin concentration more than 30 mg/dL; Serum IGF-1 concentration more than 100 mg/mL;

Performance status:	Not specified
Hepatic:	Not specified
Renal:	Not Specified
Autoimmune:	No active autoimmune, inflammatory or infectious disease at least 6 months prior to test.
Diet:	No unusual dietary restrictions at least 3 months prior to test.

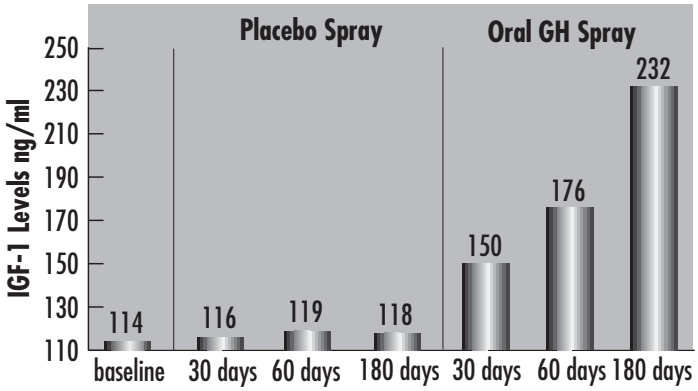
Summary

200 healthy patients were screened and tested (112 females and 88 males). No change in diet was advised, however, it was noted that all patients ate an average of 3 meals per day with approximate intakes of 3000 to 4000 calories.Testing began with a prescribed dosage of 3 sprays in the morning within one hour of awakening (equaling 2000ng of hGH) and 3 sprays in the evening immediately before retiring (totaling 4000ng of hGH per day) seven days per week.

IGF-1 Levels - Males



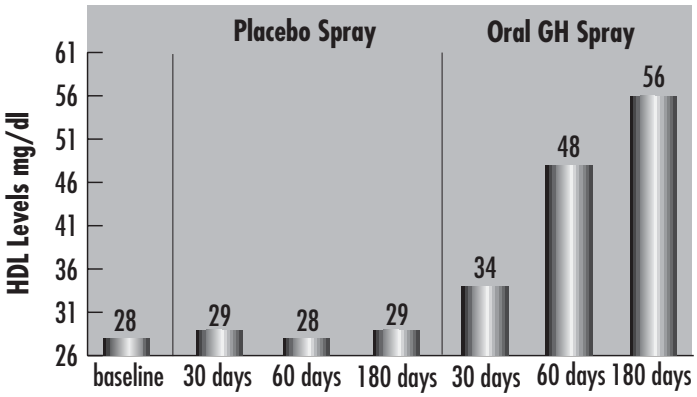
IGF-1 Levels - Females



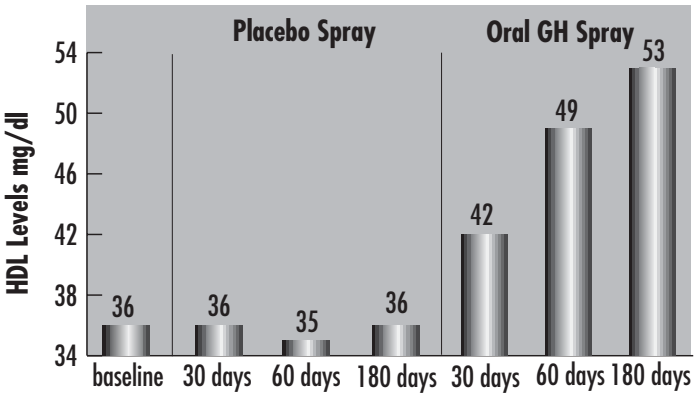
IGF-1 testing is presently the standard accepted procedure for evaluating the secretion of human growth hormone from the anterior pituitary gland. Patients were pre-examined as to determine a baseline IGF-1, 114.26 ng/ml (+/- 8.54) in 112 females (average age 51) and 135.22 (+/- 1.94) in 88 males (average age 48). 30 days after test inception, non-placebo female patients showed IGF-1 levels elevated 30 percent over baselines, 149.85 ng/ml females and 176.31 ng/ml non-placebo males. IGF-1 levels were tested after 60 days and again displayed elevated increases now 53 percent over baselines, 175.63 ng/ml females and 209.59 ng/ml males. At the end of the six-month study IGF-1 levels had increased over 102 percent over baseline in females (232.12 ng/ml) and 109 percent over baseline in males (284.05 ng/ml).

Patients on Placebo incurred dramatically different results. 30 days after inception, female/male patients IGF-1 levels were elevated or lowered +/0 2 percent over/under baselines. IGF-1 levels were tested after 60 days and again displayed on average, 4 percent over baselines. At the end of the six-month study IGF-1 levels in placebo patients averaged less than 3 percent increase over baseline.

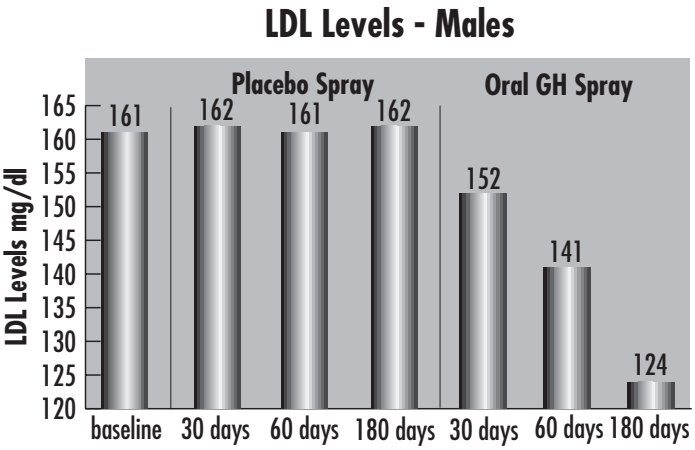
HDL Levels - Males

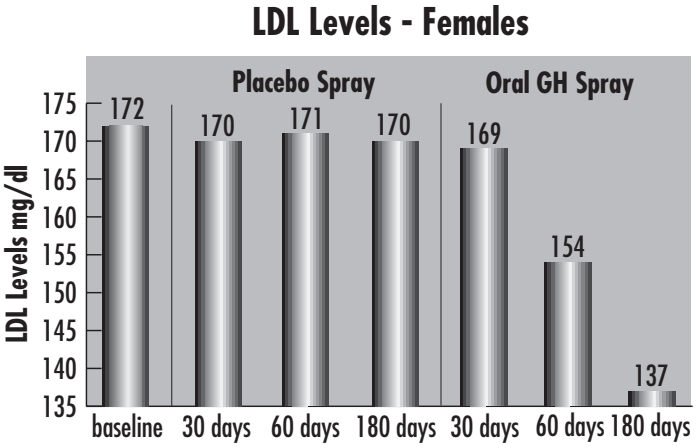


HDL Levels - Females

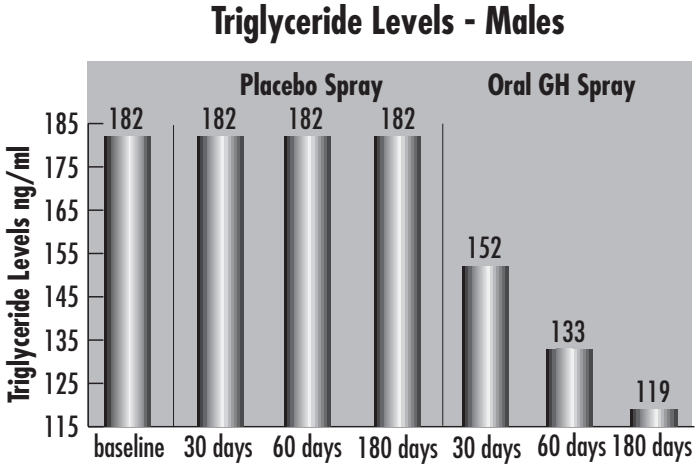


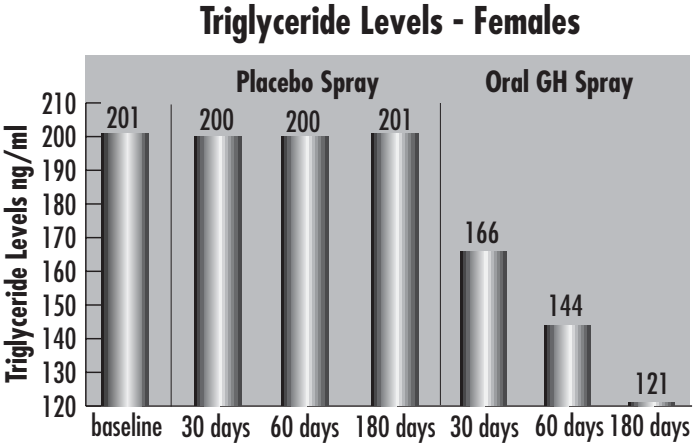
Patients were pre-examined to determine a baseline HDL level, 36 mg/dl in females and 28 mg/dl in males. 30 days after test inception, testing non-placebo female patients, HDL levels were 42 mg/dl and non-placebo males were 34 mg/dl. HDL levels were tested after 60 days and again displayed elevated increases over baselines, 49 mg/d/ females and 48 mg/dl males. At the end of the six-month study, HDL levels had increased over 47% over baseline in females (53 mg/dl) and 93% over baseline in males (56 mg/dl).





Patients were pre-examined to determine a baseline LDL level, 172 mg/dl in females and 161 mg/dl in males. 30 days after test inception, testing non-placebo female patients, LDL levels were 169 mg/dl and non-placebo males were 152 mg/dl. LDL levels were tested after 60 days and again displayed reduced levels over baselines, 154 mg/d/ females and 141 mg/dl males. At the end of the six-month study LDL levels had decreased over 20% under baseline in females (137 mg/dl) and 23% under baseline in males (124 mg/dl).





Patients were pre-examined to determine a baseline triglyceride level, 201 mg/dl in females and 182 mg/dl in males. 30 days after test inception, testing non-placebo female patients, triglyceride levels were 166 mg/dl and non-placebo males were 152 mg/dl. Triglyceride levels were tested after 60 days and again displayed marked decreases over baselines, 144 mg/d/ females and 133 mg/dl males. At the end of the six-month study triglyceride levels had decreased over 40 percent under baseline in females (121 mg/dl) and 35 percent under baseline in males (119 mg/dl).