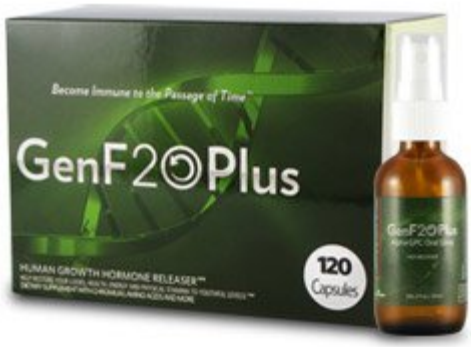
Discussion and overall conclusions Of The Genf20 Plus Clinical Study

The current study was undertaken with postulated role of GenF20 Plus in stimulating anterior pituitary gland to secrete more human growth hormone, which when released into the blood stream stimulates the liver to produce IGF-1, the primary mediator of the effects of GH. Thus the study was undertaken to evaluate efficacy and safety of GenF20Plus in improving serum IGF-1 levels and thereby improve quality of life by improving memory, libido, energy levels, sleep and body weight. The outcome variables were BMI, waist circumference, body fat and lean body mass to assess effect on body weight. The variables memory, libido, energy levels and quality of sleep were assessed through Quality of Life questionnaire. Also global assessment by subjects was used to get overall understanding.



The serum IGF-1 levels from baseline to end-of-treatment did increase more in the active group than in the placebo group. But the increase in levels was neither clinically nor statistically significant. The serum IGF-1 levels are known to decrease with increasing age. Hence to avoid dilution of data, subgroups were made with cut off as 40 years. ANCOVA was performed to adjust the baseline variations for both the sub groups. In the subgroup age≥40 years, a statistically significant increase was seen in serum IGF-1 levels in the GenF20 Plus group [22.69 (28.57%)] as compared to placebo [-4.31 (-0.55%)] (p= 0.02). The significant increase in the serum IGF 1 levels in the subgroup age ≥ 40 in the active group is attributable to consumption of GenF20 plus. Prolonged usage of GenF20 plus may be able to show a clinically significant increase in serum IGF-1 levels. In the subgroup age<40 years, there was no marked change in either of the treatment groups. This could be attributed to sustained inherent mechanism of the body to be able to secrete normal levels of serum IGF-1 levels below 40 years of age. This analysis enables to postulate that GenF20Plus is able to stimulate secretion of human growth hormone and IGF 1 and this change is noticeably observed in people above 40 years of age. A long term study should be carried out to assess the safety and efficacy of GenF20 plus in increasing serum IGF 1 levels in subjects with age≥40

At the end of 12 weeks of treatment, the BMI, waist circumference, body fat and lean body mass did not show a significant increase from baseline to end-of-treatment in both, the GenF20 plus and placebo group. There was statistically significant improvement in QoL variables of memory, energy level, and sleep from baseline to end of treatment in both the groups, but it failed to achieve statistical significance when compared between the two groups. Pearson's Chi square test on global assessment by subjects did not show a significant difference (p=0.80) between the active and placebo group.

GenF20 was well tolerated by all the participating subjects. There were a total of 12 adverse events reported (7 in active and 5 in placebo group) during the study. They were mild, not related to the study drugs and were successfully resolved. No serious adverse event occurred in the study. No significant changes were observed in the hematology variables or vitals or routine urine test.

Replenishing depleting serum IGF 1 and GH levels are postulated to attain benefits of younger age and relieve signs and symptoms of HGH decline. GenF20 contains essential amino acids and other ingredients

which are known to stimulate the production and secretion of HGH from the anterior pituitary gland. It is a natural product with no known serious side effects. It is postulated to combat ageing and boost up bodily functions. GenF20 plus is not intended for the consumption in subjects with known growth hormone deficiency. Instead its consumption is postulated to increase the declining levels of growth hormone in aging subjects by stimulating the pituitary gland. There are very few options available to effectively and safely improve the growth hormone levels. Thus GenF20 plus was intended to provide solution to improve GH levels without any adverse events. HGH and IGF 1 are also used as a performance enhancing agents, to increase muscle mass and exercise endurance14. Given its potentially adverse effects, ranging from disruption of the insulin system to cancer, administration of the exogenous HGH and IGF-I is not a safe method. The growing abuse of HGH for muscle building by athletes and body builders and its related medico-legal issues also necessitates finding safe and acceptable alternative.

A preclinical study15 has shown that HGH stimulates lipolysis in obese mice and thereby reduces body weight through decrease in total body fat. Also a large number of porcine studies have shown that HGH causes loss of fat mass through inhibition of adipocyte lipogenesis by reducing insulin sensitivity and fatty acid synthase. Treating growing pigs with pig HGH showed reduction in adipose tissue by as much as 60±80% while concurrently stimulating muscle growth by 40±60%16. A clinical study by Rudman et al has shown beneficial effects of HGH administration in a group of elderly healthy men with low plasma IGF-I values, but no underlying pituitary pathology. These studies support the hypothesis that increased levels of IGF I and HGH will stimulate lipolysis and cause reduction in body fat. Approximately 70% of the daily HGH output occurs during early sleep throughout adulthood. Studies have shown decreased HGH levels in insomniacs7. There is also age related reduction in cognitive function associated with decrease in HGH levels8. Studies have shown improvement in cognitive functioning in HGH-deficient patients by HGH substitution10. Decrease in HGH levels cause low secretion levels of sex hormones; thereby decreasing libido. Ageing is also attributed to cause diminished energy levels12. Thus restoring HGH levels may stimulate sound sleep, improve memory, increase libido and restore energy levels.

GH and IGF-1 also have an important role in the promotion of vascular health and protect thrombotic and hemorrhagic strokes17,18. Low levels of IGF 1 have been associated with poor glycaemic control in type 2 diabetes and thereby increasing risk of cardiovascular diseases. Also it is known to suppress myocardial apoptosis and improve myocardial function19. Low serum IGF-I levels is also postulated to be associated with reduced T-cell mediated immunity in elderly20. Thus GenF20 plus by increasing serum IGF 1 levels may be able to provide health benefits to the aging population and prevent disease progression.

The present study has not shown improvement in all the parameters assessed in such short duration. The present study failed to show considerable reduction in BMI or waist circumference or body fat in both active and placebo groups. Parameter of sleep, memory, libido and energy levels also did not show substantial improvement. Improvement in all of the above parameters is difficult to attain in short duration of 12 weeks. The longer the duration of these impairments, longer will be the time required to attain normalcy or perceivable benefits by any agent. The fact that serum IGF 1 levels have increased with statistical significance in the sub group with age≥40 is an indication that prolonged usage of GenF20 Plus may show improvement in other parameters as well.

There is no single study in literature which has assessed improvement in all the above parameters together. Thus the duration of treatment for this pilot study was not chosen on a sound and validated

rationale. Individual studies have shown efficacy of increased HGH levels to improve sleep quality, increase energy levels, and improve memory and libido. Thus prolonged consumption of GenF20 plus should increase HGH and IGF-1 levels and manifest improvement in the quality of life parameters. GenF20 plus may be required to be consumed for an extended period of time to show any considerable improvement in weight and body fat. In summary, GenF20 plus may not have delivered the projected efficacy results in this study, but is certainly worthy of further exploration as a potential agent to make quality of life better in overweight and aging population. To try Genf20 Plus risk free for 60 days go to http://www.perimeterinstitute.com/genf20home.html!