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Stimulation of hair growth in humans by cell-secreted proteins: A Phase I/II Trial

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We have evaluated a bioengineered human cell-derived formulation, termed Hair Stimulating Complex (HSC), on the effects of hair growth activity in male pattern baldness. HSC is produced by cells grown on beads in hypoxic bioreactors and contains cytokines including KGF, VEGF, and follistatin. Follistatin antagonizes activin and BMPs, which maintain the quiescent state of hair follicle stem cell proliferation. We hypothesized that injection of this medium may increase the supply of progenitor and transit amplifying keratinocytes provided to the growing hair shaft, leading to an increase in the thickness of the hairs and a reversal of the miniaturization process. In a pilot study of 26 males with androgenetic alopecia, a single treatment, consisting of four 0.1cc injections of HSC into the scalp, caused a statistically significant increase in hair density (p=0.0249) and terminal hairs (p=0.029) at 3 months, and a reduction in vellus hairs which is consistent with vellus-terminal conversion. At 1 year, a similar increase in hair thickness density (p=0.032) as well as an overall increase in hair count was seen, consistent with an increased rescue of miniaturizing follicles. A Phase I/II clinical trial was undertaken to further assess the safety and efficacy of HSC in humans. The study design was a two site, double-blind, randomized, in-patient placebo-controlled clinical trial. After obtaining informed consent, 56 healthy male subjects with androgenetic alopecia between 21-65 yrs of age were enrolled. A treatment of the HSC formulation, consisting of eight 0.1cc injections, was administered into a designated randomized region of the scalp at baseline, with a parallel region receiving equal amounts of medium without growth factors. A second identical treatment was administered at 6 weeks. To assess the hair growth effects of HSC, hair measurements were performed using Trichoscan image acquisition and analysis at various time points following treatment. At 3 months, a 10.45% increase in total hair count (p=0.0006) was seen, along with a 34.8% increase in terminal hairs (p=0.0009), as well as a 14.23% increase in hair thickness density (p=0.0001) and a 3.5% increase in hair shaft diameter (p=0.022) within the HSC-treated sites. Following the pattern seen in the pilot clinical trial of HSC, this significant efficacy at 3 months is an indication that further increased hair growth will be seen at later timepoints, with the next efficacy follow-up at 6 months. No drug related adverse reactions were reported and urine and blood toxicology testing at baseline, 4, and 12 weeks demonstrate that HSC is safe. The efficacy results seen with HSC in this human clinical trial represent a novel regenerative medicine approach in hair growth treatment by using bioengineered, cell-derived growth factors that achieve trichostimulation in vivo. These results represent an important advance in the treatment of androgenetic alopecia.

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