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SYNTHETIC HUMAN GROWTH HORMONE

By means of recombinant DNA techniques, the gene for human growth hormone (hGH) has been expressed in *Escherichia coli* and the methionyl analogue (met-hGH) has been derived and purified. The biopotency of purified met-hGH (2 U/mg) is equivalent to that of pituitary-derived hGH (pituitary hGH) in stimulating weight gain, widening the tibial epiphysis, and raising serum free fatty acid concentrations in hypophysectomised rats. In adult human beings, met-hGH is equipotent with pituitary hGH in raising plasma somatomedin-C concentrations and in promoting nitrogen retention. Likewise, met-hGH is indistinguishable from pituitary hGH in its ability to compete for binding to cell membrane GH receptors and to polyclonal GH antibodies.

In October, 1981, clinical trials directed at determining the efficacy and safety of met-hGH as a therapeutic agent were begun in hypopituitary children in 12 US medical centres. This report describes the results of those trials, which now include 46 children, some treated with met-hGH for as long as 4 years. 36 children with growth hormone deficiency were treated for up to 48 months with met-hGH synthesised by DNA recombinant methods. The growth rate for these children increased from $3 \cdot 2 \pm 1 \cdot 1$ cm/yr to $10 \cdot 5 \pm 2 \cdot 2$ cm/yr (mean$\pm$SD). This was similar to the effect of pituitary hGH in ten GH deficient children, $3 \cdot 8 \pm 1 \cdot 0$ to $10 \cdot 1 \pm 1 \cdot 1$ cm/yr. Serum somatomedin C rose from $0 \cdot 26 \pm 0 \cdot 23$ U/ml to $0 \cdot 79 \pm 0 \cdot 53$ U/ml after 6 months of met-hGH therapy, similar to the effect of pituitary hGH. The incidence of antibody formation to methionyl-hGH was higher than that observed with pituitary hGH (Kabi) but poor growth was observed only in the one patient on met-hGH who acquired high-titre high-binding-capacity antibodies to hGH. No consistent changes in levels of antibodies to *E. coli* proteins were detected. No other allergic manifestations or systemic side-effects were demonstrable.

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