

unit and a repeat of the model day study. rhIGF-I/IGFBP-3 treatment decreased 24-hour insulin requirements by 49% (27.3±12.8 vs. 53.6±18.7 U/24 hr; p<0.001) and reduced mean home glucose values by 23% (144±73 vs. 187±95 mg/dL; p<0.02). All patients receiving rhIGF-I/IGFBP-3 noted a decrease in insulin requirements. The accuracy of the insulin diaries submitted by the patients was confirmed by measuring free insulin in the blood circulation, which was reduced 47% (20.1±9.0 vs. 37.5±15.9) in patients receiving rhIGF-I/IGFBP-3. Growth hormone, known to substantially contribute to insulin resistance, was reduced by 77% in patients receiving rhIGF-I/IGFBP-3 (0.55±0.23 vs. 2.48±0.73).

No significant drug-related side effects were observed. Subjects did not experience edema, jaw pain, or headache-side-effects almost invariably observed when human subjects are treated with substantial doses of free IGF-I. rhIGF-I/IGFBP-3 produced the desirable biological effects of IGF-I in diabetic subjects, but with a surprising lack of side effects.

The patents, patent applications, and publications cited throughout the disclosure are incorporated herein by reference in their entirety.

The present invention has been detailed both by direct description and by example. Equivalentents and modifications of the present invention will be apparent to those skilled in the art, and are encompassed within the scope of the invention.

I claim:

1. A method for treatment of diabetes mellitus, comprising:

administering an effective amount of IGF-I/IGFBP-3 complex to a subject suffering from symptoms or complications of diabetes mellitus.

2. The method of claim 1 wherein said IGF-I/IGFBP-3 complex is human IGF-I/IGFBP-3 complex.

3. The method of claim 2 wherein said IGF-I/IGFBP-3 complex is recombinant human IGF-I/IGFBP-3 complex.

4. The method of claim 1 wherein said diabetes mellitus is type I diabetes mellitus.

5. The method of claim 4 wherein said type I diabetes mellitus is insulin resistant type I diabetes mellitus.

6. The method of claim 1 wherein said diabetes mellitus is type II diabetes mellitus.

7. The method of claim 6 wherein said type II diabetes mellitus is insulin resistant type II diabetes mellitus.

8. The method of claim 1 wherein said diabetes mellitus is type A insulin resistance diabetes mellitus.

9. The method of claim 1 wherein said IGF-I/IGFBP-3 complex is administered on a continuous administration schedule.

10. The method of claim 1 wherein said IGF-I/IGFBP-3 complex is administered on a discontinuous administration schedule comprising cycles which include an on period wherein IGF-I/IGFBP-3 complex is administered and an off period wherein IGF-I/IGFBP-3 complex is not administered.

11. The method of claim 10 wherein said off period is less than said on period.

12. The method of claim 10 wherein said off period is greater than said on period.

13. The method of claim 10 wherein said off period is equal to said on period.

14. A kit, comprising a package comprising IGF-I/IGFBP-3 complex; and instructions for use of said IGF-I/IGFBP-3 complex for the treatment of diabetes.

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