Subjective Reduction in Symptoms of Chronic Fatigue Syndrome following Long-Term Treatment with a Porcine Liver Extract: A Phase 1 Trial

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Subjective Reduction in Symptoms of Chronic Fatigue Syndrome Following Long-Term Treatment with a Porcine Liver Extract: A Phase 1 Trial. THOMAS STEINBACH, WILLIAM HERMANN, CARL LAWYER, DAVID MONTEFIORE, SUDHAKAR WAGLE, ALI GAWISH, AND DAVID FERGUSON. *From the Memorial City Medical Center, Houston, Texas; the Department of Surgery, Duke University Medical Center, Durham, North Carolina; and the Schwarz-Pharma Company, Milwaukee, Wisconsin.*

A prospective preliminary study of the use of Kutapressin (Schwarz Pharma, Milwaukee, WI), a porcine liver extract approved for humans, in the treatment of chronic fatigue syndrome (CFS) examined subjective reduction in symptoms on a five-category functional symptom scale via assessment by both patients and physicians. Kutapressin, (2 mL im injections) had been used since 1940 without reports of significant toxic effects [1] to treat patients in the United States who had conditions such as herpes zoster.

Therapy with Kutapressin (2 mL im daily) was administered for 25 days; this dosage was followed by 2 mL of drug administered every other day for 50 days and then by 2 mL of drug administered three times a week for 105 days, for a total of 95 injections over the 180 days from initiation of therapy. If a minor setback occurred the dosing regimen was started over again, and treatment was continued beyond 6 months if continued progress was considered likely by the patient and physician.

One hundred eleven (85%) of 130 CFS patients who had chronic fatigue for at least 4 months reported notable (only slight residual symptoms) or marked (asymptomatic) reduction in symptoms while receiving therapy with Kutapressin. Forty-two percent of patients reported complete remission of symptoms while receiving Kutapressin. The median number of injections required for moderate reduction in symptoms was 31; for notable reduction, 60; and for marked reduction (i.e., complete remission of symptoms), 85 (figure 1).

Minor setbacks during therapy were reported by 21 (16%) of 130 patients; of these 21 patients, 12 eventually reported notable reduction in their symptoms and four reported marked reduction. Of the 111 patients reporting notable or marked reduction in symptoms, 103 achieved this reduction within the first 6 months of treatment while the remaining 8 patients required treatment beyond 6 months. Of the 55 patients who reported marked reduction in symptoms, 36 did so within the first 6 months of treatment. Seventeen patients reported only moderate reduction in symptoms, and two reported a slight reduction. In an earlier study (before 1990) by our group in which less-frequent and fewer doses of Kutapressin (2 mL im daily for 10 days followed by this dosage three times a week) were administered, 201 (74%) of 270 patients reported comparable notable or marked reduction in symptoms.

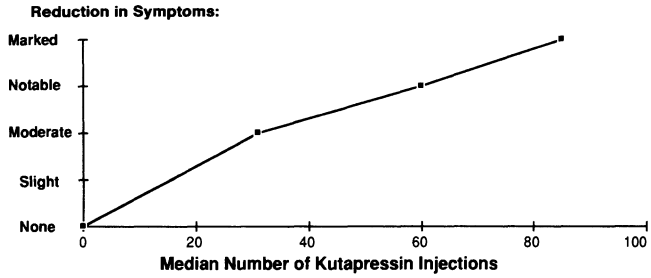

Figure 1. Reduction in symptoms of CFS after injections with Kutapressin.

In the present study, Kutapressin appeared to subjectively decrease the clinical symptoms of most patients with CFS. However, since the etiology of CFS is not known and there is no objective measure of CFS symptoms available, the meaning of this finding is unclear. Since there was no placebo control group, it is possible that all reported reduction in symptoms was due to a placebo effect. Although the subjective reduction in symptoms (with Kutapressin treatment) reported herein is consistent with Kutapressin's reported in vitro activity against Epstein-Barr virus and human herpes virus type 6, treatment for CFS can only be evaluated with certainty when the etiology of CFS is fully known and objective measures of the severity of disease due to CFS are available.

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