Randomized, double-blind, sequential, multicenter clinical trial of two doses of Sygen versus placebo.

To determine efficacy and safety of Sygen in acute spinal cord injury.

An earlier, single-center trial in 28 patients showed an improvement (50.0% vs. 7.1%, P = 0.034) in marked recovery with Sygen.

Standard clinical trial techniques.

The prospectively planned analysis at the prespecified endpoint time for all patients was negative. There was a significant effect in all patients in the primary outcome variable (the percentage of marked recovery) at week 8, the end of the dosing period. There was a significant effect in all patients in the time at which marked recovery is first achieved. Restricted to severity Group B, which has small sample size, the primary efficacy analysis showed a trend but did not reach significance. There is a large, consistent and, at some time points, significant effect in the primary outcome variable in the nonoperated patients through week 26. The American Spinal Injury Association motor, light touch, and pinprick scores showed a consistent trend in favor of Sygen, as also did bowel function, bladder function, sacral sensation, and anal contraction. The less severely injured patients appeared to have a greater beneficial drug effect. Evidence against an effect of Sygen was minimal and scattered.

Although not proven in the primary efficacy analysis of this trial, Sygen appears to be beneficial in patients with severe spinal cord injury [1)].

1)
Geisler FH, Coleman WP, Grieco G, Poonian D; Sygen Study Group. The Sygen multicenter acute spinal cord injury study. Spine (Phila Pa 1976). 2001 Dec 15;26(24 Suppl):S87-98. PubMed PMID: 11805614.