

2017 RESULTS FOR THE LOWER EXTREMITY PAIN MEDICARE TRIAL

We were fortunate to be among the sites chosen to engage as a study site for national clinical trial 01979367, sponsored by the American Association of Sensory Electrodiagnostic Medicine (AASEM). This is a summary of our findings from 2017.

Patients who enrolled in the clinical trial had burning, stinging, numb, or painful feet and had damaged pain fibers in their feet or legs. These symptoms were often accompanied by altered gait, balance, and restless leg symptoms, though these were not the primary enrollment requirements. The purpose of the clinical trial is to improve blood flow to pain fibers in legs and feet, and to reset and restore proper nerve function in the lower extremities.

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We tested a total of 34 patients from May 11, 2017 through December 10, 2017. Seven patients did not qualify or declined entrance into this study. Twenty-seven patients (44-88 years old) were enrolled, and a total of 50 individual nerves were studied.

32 of the 40 nerve studies completed showed more than 60% improvement. This is more than 80% improvement for the patients overall. Out of the 40 completed tests, 39 showed overall improvement to some degree. This is a 97% overall improvement of studied nerves. Eased restless legs symptoms and also improved sleep were noted in over 50% of our patients. We also generally observed that younger patients were quicker to respond to therapy.

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Longer term data will need to be reviewed to assess implications in this regard.

According to Dr. Gerstenberg, "This Medicare clinical trial has done wonders to lower the need for pain medication, while improving balance, sleep, restless legs and overall function in nearly every patient. While it is not a miracle cure, I think most would agree that for severe pain like neuropathy, less pain with less medications is a no-brainer. I hope all physicians can do these treatments in regular practice someday, and not need to be done only in a Medicare clinical trial."