

Dear (Patient):

Our center is taking part in a new clinical trial research study for patients with painful Diabetic Peripheral Neuropathy, also referred to as DPN.

The main purpose of this study is to look at how well the drug under study works on improving diabetic peripheral neuropathy pain, when compared to placebo. Currently there are only 3 FDA approved medications to treat diabetic peripheral neuropathy.

You may be able to take part in the study if you:

- are 18 years of age or older
- have type I or II diabetes mellitus for at least 6 months
- have had diabetic peripheral neuropathy for at least 6 months

The study will last approximately 28 weeks. You will have up to 13 clinical visits in office, as well as 1 phone call follow up visit. Travel compensation is also available. After an initial screening visit, to ensure that you meet all of the necessary safety criteria, patients will participate in a pain observation period in which you will record your pain rate in an electronic diary daily. After this observational period, you will be having the regularly scheduled visits.

It is important to note that taking part in a study will not impact the standard visits you have with your own healthcare providers. Our team will regularly update your doctor on your study status and we will also share copies of any labs or eye exams that are completed during the trial

Please feel free to contact me if you have any questions, or if you would like to learn more about this study. If you contact me, you can still choose not to join the study.

Thank you,  
Dr. Laxmaiah Manchikanti