



Dear Patient:

Our center is taking part in a new study, FOCUS by Novo Nordisk, for patients with type II diabetes. When patients have type II diabetes it can cause many different health problems, including vision changes like diabetic retinopathy.

The main purpose of the FOCUS study is to look how well semaglutide works on improving blood sugar readings over time, when compared to placebo, and the effects it has on diabetic eye complications. Semaglutide, the study medication, is one that is already FDA-approved for the treatment of type II diabetes in the US. The trade name of this medication is Ozempic® and is a once weekly, non-insulin, injectable medication.

Approximately 1,500 adults from all over the world will take part in this study. You may be able to take part in the FOCUS Study if you:

- are 18 years of age or older
- have had type II diabetes mellitus for at least 10 years
- uncontrolled type II diabetes (HbA1c between 7.0 – 10.0 %)

The study will last approximately 5 years. You will have up to 16 clinic visits, however the trial does allow for alternative scheduling when needed. Travel assistance is also available. At 13 of those 16 clinic visits, patients will be referred to the study ophthalmologist to complete a series of eye exams. A screening visit would be done first to ensure that you meet all of the necessary safety and eye criteria. If you qualify after the screening visit, you will begin the study medication at the second visit. If you do decide to take part in this study, all study medication, eye exams, diabetic testing supplies and tests will be provided at no cost. It's 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. Cynthia Bowman-Stroud, Principal Investigator & Allie Guill, Lead Clinical Research Coordinator

270-441-4606 (or call/text 270-994-9926)