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Northeast Iowa Medical Foundation Clinical Study of Type Two Diabetes

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SOTA GLIM CLINICAL RESEARCH STUDY

Blake Thomas
University of Northern Iowa
McNair Director: Dr. Neivita Bueno Watts
Research Mentor: Dr. Jim Hoehns
Description of Research facility

- Northeast Iowa Medical Foundation
- Dr. James Poock
- Dr. Jim Hoehns
- Head research coordinators Jessica Schwake BSN RN
- Karrie Cheeseman BSN RN
Fasting glucose measurement- a patient making sure not to have eaten anything in a 24 hour period before checking their blood sugar.

Titrating- determining the levels in which to raise or lower a medication.

Hemoglobin a1c- a test measuring your average blood glucose during the past three months.

Placebo medication- a medication used to make sure that each patient routinely taking their medication.

Body mass index- weight to height ratio.

Adverse events- any event that could have possibly led the patient into the emergency room.
The Benefits of this Study

- There is a total of 13 visits. 2 of the visits are made through telephone calls. The other 11 visits are actual in person encounters where the patient will receive a compensation of $50 each time.
- Sanofi sponsored study so this drug manufacturing company will gain exposure amongst patients and health professionals.
- There can be a possibility that the health professionals with type 2 diabetes patients can find a more beneficial blood sugar control medicine.
This study strives to deliver innovative solutions
A commitment to high standards of manufacturing excellence to prevent and manage a broad spectrum of medical conditions
A study working with patients that have type 2 diabetes
It is an analyzed study to see the difference in quality between Sotagliflozin and Glimepiride and to see which one will lower patients blood glucose levels more effectively.
A 52 week Randomized double-blind double-dummy, active and placebo-controlled, parallel group study
This study strives to deliver innovative solutions
Medication being taken during 52 week process

- Tested drug- Sotagliflozin 400 mg and 200 mg, given as 200 mg tablets
- Control drug- Glimepiride 1 mg (starting dose) titrated up to 6 mg (glimepiride capsules: 1, 2, and 4 mg dose strengths)
- Placebo- Sotagliflozin-matching placebo (200 mg) and glimepiride-matching placebo
My Job as a Research Intern

- Screening individuals who could possibly be eligible for the clinical study
- Contact certain publication agency and allow them to know that we are holding a clinical research
- Log in information from visits that have taken place
- Order labs necessary for each visit
Inclusion Criteria for Being In Study

- Type 2 diabetes
- Taking treatment of stable dose of Metformin at a stable dose of 1500 mg/day
- Age 18 years or older
- No Body Mass Index (BMI) ≤20 or ≥45 kg/m²
- Be able to self monitor and record fasting glucose levels
- No weight loss medications or no weight change of 5 kg or more during the past 12 weeks
- Hemoglobin a1c levels between 7.0%-10.0%
Exclusion Criteria for Study

- History of drug or alcohol abuse within 6 months prior to screening
- Previous use of any types of insulin >1 month (at any time, except for treatment of gestational diabetes)
- History of glucose-6-phosphate dehydrogenase (G6PD) deficiency
- History of severe hypoglycemia resulting unconsciousness, seizures or hospitalization within 6 months
Methods of Recruitment

- Identifying other areas that have a high population of certain type 2 diabetic patients
- Population of age difference with type 2 diabetes
- Analyzing which hospitals have more use of metformin amongst their patients through pharmacy records
Methods of the Study

- Having both the study being double blind will give a more beneficial and possibly more relevant measure of what medication will work best for each patient.
- Keeping track of the blood glucose levels in a journal that is given to them will make for more proper measurements to keep record on.
This clinical research that I have been able to be apart of has allowed me to analyze certain morbidity of chronic diseases specifically type 2 diabetes. Even with this being a year around study the factors needed to be put forth in order to create study. It gave me great excitement for my future passions in pursuing a graduate level education in Epidemiology.