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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

NORTHEAST IOWA  
FAMILY  
MEDICINE  
RESIDENCY



# Important terms

- ▣ Fasting glucose measurement- a patient making sure not to have ate 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





# What is this study?

- ▣ 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)  $\leq 20$  or  $> 45$  kg/m
- ▣ 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



# Conclusion

- ▣ 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.

