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A. Study Purpose and Rationale

The purpose of this study is to determine if there is an overall benefit to intensive glycemic control in the non-ICU inpatient adult diabetic population.

B. Study Design and Statistical Analysis

This is a randomized, double-blinded placebo controlled trial of 500 adult diabetic patients admitted to the hospital for any reason other than the exclusion criteria diagnoses listed in section G. The patients will be stratified based on presence or absence of at least one long term complications from diabetes, (renal insuffiency with Cr. >1.5, retinopathy, or neuropathy) as an indirect measure of overall level of control. Half the group will be randomized to the intensive glycemic control arm, with goal glucose <130, to be achieved with insulin drip according to a written protocol. The other half of the group will receive subcutaneous insulin via sliding scale for goal glucose <250 which approximates current practice. (The patients with at least one complication will be separately randomized into the two groups.) Both groups will be written for sliding scales and the non-insulin gtt group will have a placebo saline bag with KVO orders.

The study is designed to have 80% power, testing at p=0.05. To attain this power, 144 patients are needed in each group according to unpaired t-test for the primary endpoint which is a continuous variable—length of hospitalization in days. For the secondary endpoint, presence or absence of nosocomial infection, a chi-square analysis requires 222 patients in each group. In order to account for hospital deaths, withdrawal from study etc, 500 patients overall will be recruited for the study.

C. Study Procedure

The study will be done over a 6 month period. The procedures involved are placement of peripheral IV for all patients, which produces mild discomfort with insertion, and requires frequent (q 3 hour) fingersticks to measure blood glucose, which is an inconvenience. Standard clinical care would assess fingersticks twice daily at the minimum. Standard use of an insulin drip is usually reserved for patients in DKA/HHNK, or difficult to control blood glucose levels.

D. Study Drugs

N/A

E. Medical Device

N/A

F. Study Questionnaires

N/A

G. Study Subjects

Inclusion criteria: All adult diabetic patients admitted to the hospital for any reason
Exclusion criteria: Type I diabetics, Gestational diabetes, admission diagnosis of DKA/HHNK, admission diagnosis of MI, previous hospitalization within past 1 month, CHF with EF<30% or requiring outpatient inotropic support

H. Recruitment of Subjects

Patients would be approached about the study once they have arrived to the floor by the admitting MD. It would be difficult to contact the primary care doctor prior to admission, given that a large number of patients admitted to CPMC do not have a primary care doctor, or that doctor is unavailable to speak with at time of recruitment.

I. Confidentiality of Study Data

A unique code will be assigned to all study subjects accessible only to investigators and research assistants. This data will be stored on a secure computer outside the hospital.

J. Potential Conflict of Interest

There is no potential conflict of interest.

K. Location of the Study

The study is to take place at CPMC in a clinical care area.

L. Potential Risks

The greatest potential risk is to patients randomized to the insulin gtt arm who may become hypoglycemic. This can be reversed with food, D50, or glucagon depending on the level. However, severe hypoglycemia can induce coma, seizures and ultimately be fatal. Incidence of mild hypoglycemia (glucose >55) and severe (glucose <55, mental status change, seizure, coma, death) will be recorded.

M. Potential Benefits

The potential benefit is shortened hospitalization and therefore decreased risk for nosocomial infections, which are often more severe in diabetics.

N. Alternative Therapies

N/A

O. Compensation to Subjects

There will be no compensation.

P. Costs to Subjects

There will be the additional cost of the independent MD available to monitor for hypoglycemic episodes and potential additional orders needed. It will also be more labor intensive for the medical staff.

Additional people will be needed to obtain and record fingersticks. Nursing staff will be required to monitor patient more frequently and to adjust the insulin drip as needed which is more labor intensive.

Q. Minors as Research Subjects

N/A

R. Radiation or Radioactive Substances

N/A