Glucose Control Protocol HGIM Meeting 8/2/99

Attendees:

Jamie Dananberg, Clinical Research Physician Endocrinology
Charles Beasley, Clinical Research Fellow, Zyprexa Product Team
John Krueger, Clinical Plans Manager, Zyprexa Product Team
Kim Spencer, Clinical Research Associate, Zyprexa Product Team
Anna Thornton, Clinical Research Associate, Zyprexa Product
Julie Bennett, Clinical Research Associate, Endocrinology

Absent:
Craig Mallinckrodt, Statistician Zyprexa Product Team

It was clear that there is a financial opportunity to get the study up and running this year.

Most likely the study will be placed at IU, with the PI being Alain Baron, Chief of Endocrinology

In a recent review of the Zyprexa database,

199 cases of Type II diabetes mellitus (DM) were identified:
        Out of these 199, 8 patients were clearly non-diabetic previously.

        1/3 of these patients had a history of DM (n= 73)

        126 patients were without previous DM or with an unknown history

Ranges:

126-300 mg/dl
300-600 mg/dl
>600 mg/dl
Ketonic
Coma

Need to distinguish between hyperosmolar coma and ketoacidosis.

Dr. Dananberg raised the question of whether we have analyzed thirst or food craving. Zyprexa has not done so to date.

The proposed study would be a Lilly sponsored study (i.e. the data would be coming in house).
- Ideally 3 weeks in duration, however 2 weeks may be sufficient
- 3 arm study

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- ❖ Risperidone 4-6 mg/day, titrated in 2 mg increments
- ❖ Zyprexa 10 mg/day, titrated in 5 mg increments
- ❖ Chlorpromazine 300 mg/day titrated in 100 mg increments
- ❖ Potentially a control arm

- Single blind study (both the patient and the person doing the clamping will not know what drug was given)

Redacted

Clamp   approximately [×] per clamp x 2 per patient = [×] per patient
Radio Isotope approximately [×] per administration x 2 per patient = [×] per patient
IVGTT   approximately [×] per patient x 2 per patient = [×] per patient

Jamie will follow up with Alan regarding logistics and study design
Jamie, Craig, and Charles need to meet to discuss statistical issues

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