

The Effect of Short Term Atypical Antipsychotic Administration Compared to Placebo on Hepatic Insulin Extraction and Muscarinic Mediation of Beta-Cell Function: A Small Mechanistic, Single-Site Study

Principal Investigator

Michael Rickels, M.D., MS

Study Title:

The Effect of Short Term Atypical Antipsychotic Administration Compared to Placebo on Hepatic Insulin Extraction and Muscarinic Mediation of Beta-Cell Function: A Small Mechanistic, Single-Site Study

Purpose:

The purpose of this research study is to determine the effects of a certain class of drugs called "atypical antipsychotics", on insulin release and on insulin's response to blood sugar. We believe some of these types of drugs have an effect on insulin release. We also believe these drugs decrease insulin sensitivity, which refers to insulin's ability to lower blood sugar.

The drug we will test is olanzapine. Olanzapine is an approved drug for the treatment of schizophrenia (a severe mental disorder). Recent data suggests that giving a patient olanzapine may cause weight gain. Olanzapine may also increase insulin release and decrease insulin sensitivity contributing to the development of diabetes. It is not currently known if the effect of olanzapine on insulin release and insulin sensitivity are a result of weight gain or if the drugs have an effect on insulin even without weight gain. In this study we want to determine if olanzapine has an effect on insulin release and insulin sensitivity in healthy people who do not gain weight. This will allow us to determine if the drug itself is causing a problem with insulin rather than the disease or weight gain. Therefore, we will compare the effect of olanzapine to placebo (sugar pill) and examine their effects on insulin release and insulin sensitivity in healthy, normal weight volunteers.

Brief Description

All people enrolled in the study will have 3 separate visits to the Clinical and Translational Research Center (CTRC) at the Hospital of the University of Pennsylvania, located at 34th and Spruce Streets in Philadelphia. If you are enrolled in the study, you will be asked to:

- o Take olanzapine or placebo by mouth for 10 days
- o Have blood drawn from your arm for an extended period of time.

You will stay in the CTRC for 12 days and 12 nights. During this time, we will ask you to undergo several kinds of tests that will show how your body responds to olanzapine. While you are an inpatient, you will be required to stay in the hospital, but will be able to receive visitors during regular visiting hours (11AM-8PM).

Eligibility

Men and women ages 18-40

BMI 19-24.5kg/m²

Subjects capable of giving informed consent, with no past or present psychiatric history

Only women on oral contraceptives with constant dosing regimens or Depo-Provera
No medications except as above noted
Weight stable

Compensation (if applicable)	\$3005.00
Name	Erica Alshehabi
Phone	(215) 746-2086
Email:	nights12@mail.med.upenn.edu