

**INSTRUCTIONS: Please submit an STN Site Application before completing this form.
Application should be submitted online at www.stn.unc.edu/application.htm**

STUDY SYNOPSIS

Purpose

The study will compare the effectiveness of antipsychotic medications for patients with schizophrenia or schizoaffective disorder for whom a medication change may be indicated because of an increased risk of cardiovascular disease.

Total Enrollment: 300

Study start: January 2007; **Expected completion:** July 2008

Metabolic abnormalities associated with cardiovascular morbidity and premature mortality are more common in patients with schizophrenia than in matched controls. Although there is some evidence that patients with schizophrenia have intrinsic abnormalities in lipid and carbohydrate metabolism, some antipsychotics (i.e., clozapine, olanzapine, quetiapine, and risperidone) are associated with increased rates of metabolic abnormalities that predispose patients to cardiovascular disease.

This is an investigator-initiated clinical trial that will be conducted at research sites that are a part of the NIMH Schizophrenia Trials Network.

The aims of the study are to (1) determine the relative effects of switching to aripiprazole, versus continued treatment with olanzapine, quetiapine, or risperidone, on metabolic parameters associated with cardiovascular disease, and (2) to determine the effects of switching to aripiprazole versus continued treatment with olanzapine, quetiapine, or risperidone on the clinical stability of schizophrenic illness.

This study design is a multi-site, single-blind (rater) randomized controlled trial of 300 patients with schizophrenia or schizoaffective disorder comparing treatment with the following medications: olanzapine, quetiapine, risperidone, and aripiprazole. The study will enroll patients with schizophrenia or schizoaffective disorder for whom a medication change may be indicated because of an increased risk of cardiovascular disease in spite of adequate control of symptoms on their current antipsychotic medication. Patients who are taking olanzapine, quetiapine, or risperidone and who have a body-mass index (BMI) greater than or equal to 27 and non-HDL cholesterol greater than or equal to 160 mg/dl will be eligible. All treatments will be open label. Raters will be blinded to treatment assignment. Patients will be followed for up to 6 months.

Eligibility

Ages Eligible for Study: 18 Years - 65 Years, Genders Eligible for Study: Both

Inclusion Criteria:

- diagnosed with schizophrenia or schizoaffective disorder
- currently treated with olanzapine, quetiapine or risperidone
- BMI \geq 27
- non-HDL cholesterol \geq 160mg/dL

Exclusion Criteria:

- diabetes (FBS \geq 126) or treatment with oral hypoglycemic drug or insulin
- non-HDL cholesterol > 300 mg/dL
- serum triglycerides > 500 mg/dL
- patients in the first episode of schizophrenia or schizoaffective disorder
- known hypersensitivity to aripiprazole
- on weight loss medications

Sponsors and Collaborators:	National Institute of Mental Health (NIMH) Foundation for the National Institutes of Health Schizophrenia Trials Network
ClinicalTrials.gov Identifier:	NCT00423878

Schedule of Events

Assessments	V1 SCR	V2 BASE	V3 WK1	V4 WK2	V5 WK3	V6 WK4	V7 WK8	V8 WK12	V9 WK16	V10 WK20	V11/DC WK24
Demographics	1										
Vital Signs Screening	1										
Biospecimen Shipping Form	1					1	1	1	1	1	1
SCID/Psychiatric History	2										
Medications Eligibility Form	3										
Med History & Physical Exam	3										
Inclusion/Exclusion Criteria	3										
IWQOL-lite		1									1
Study Antipsychotic Dispensing		1	1	1	1	1	1	1	1	1	
SF-12		1									1
SURFs		1				1	1	1	1	1	1
Vital Signs Follow-up		1				1	1	1	1	1	1
Clinical Global Impressions		2				2	2	2	2	2	2
Substance Use Scale		2				2	2	2	2	2	2
PANSS		2				2	2	2	2	2	2
SAS		2					2	2			2
AIMS		2					2	2			2
Barnes		2					2	2			2
Lipid-lowering Agent Adherence		3	3	3	3	3	3	3	3	3	3
Other Medications Record		3	3	3	3	3	3	3	3	3	3
Lithium, Valproate, Topiramate		3	3	3	3	3	3	3	3	3	3
Medical Diagnoses		3						3			3
Randomization Form		3									
Study Antipsychotic Adherence			1	1	1	1	1	1	1	1	1
Global Behavioral Trt. Adherence											1
Reason for Assigned Trt. Discont.											3
Adverse Events/Side Effects						2	2	2	2	2	2
Behavioral Trt Adherence Record			1	1	1	1	1	1	1	1	1

1=Study Coordinator 2=Blinded Rater 3=Study Physician

CAMP Site Interest/Application Form

1. Introduction

Please submit an STN Site Application before completing this form.

[Click Here to Submit STN Application](#)

Please read the Study Synopsis posted on www.stn.unc.edu before completing this form.

1. Please complete the following information so that we can link your CAMP Site Application to your STN Site Application

PI First Name

PI Last Name

Institution/Location

2. Eligibility and Recruitment

Eligibility

Ages Eligible for Study: 18 Years - 65 Years

Inclusion Criteria

- diagnosed with schizophrenia or schizoaffective disorder
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Exclusion Criteria

- diabetes (FBS \geq 126) or treatment with oral hypoglycemic drug or insulin
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- known hypersensitivity to aripiprazole
- on weight loss medications

2. Do any of the Study Eligibility Criteria present difficulties that could inhibit finding/enrolling patients for the study?

No

Yes, please explain



3. Based on the inclusion/exclusion criteria, how many patients do you realistically believe your site will be able to enroll in a month?

0-1

1-2

2+

4. Are you currently conducting or expect to begin conducting any studies that would compete for this particular patient population?

Yes

No

5. Do you have any concerns with the study synopsis that would affect enrollment at your site?

3. Study Blinding

Study Blinding

Study treatments are not blinded to the patient, study coordinator, or study physician. However, some study ratings must be conducted by a rater who is blinded to the treatment condition.

- Only study coordinator and prescribing physician should know treatment condition.
- All staff must be aware that raters are blinded.
- The offices of the clinical raters should be isolated from other team members.
- Raters must not conduct any medical record reviews, etc., after randomization.
- A back-up blinded rater is needed to conduct designated ratings (PANSS, CGI, side-effects, substance use) in case primary rater becomes aware of the subject's treatment assignment.
- In order to prevent bias and to protect the blind, a study physician should not serve as a study physician for some patients and a blinded rater for others.

6. Do the blinding requirements present a problem for your site and your site personnel?

Yes

No

Comments or Questions

7. If your site does not have access to the appropriate personnel at this time, do you believe you could hire and train personnel by August 2007?

Yes

No

Questions or Comments

4. Thank You!

Thank you for taking the time to complete this survey.
We will respond to your application within 60 days.

8. Additional Comments?