U.S. Department of Health and Human Services
National Institutes of Health
NIDA NATIONAL INSTITUTE ON DRUG ABUSE
NIH... Turning Discovery Into Health

National Institute on Drug Abuse
Clinical Trials Network
6001 Executive Boulevard
Room 3105, MSC 9557
Bethesda, Maryland 20892-9557

Telephone: (301) 443-6697

Fax: (301) 443-2317

Further information on the Clinical Trials Network can be accessed through the NIDA website at **www.drugabuse.gov**.

July 2012

CTN-0052

National Drug Abuse Treatment Clinical Trials Network

Buspirone for Relapse-Prevention in Adults with Cocaine Dependence (BRAC)

Should I Join?

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE ON DRUG ABUSE

What is the BRAC study?

The chronic, destructive nature of crack cocaine dependence means that a majority of the patients who receive inpatient or residential treatment for their disorder will relapse to using cocaine within a few months of discharge.

Although the development of medications to help cocaine-dependent patients achieve—and maintain—a cocaine-free lifestyle has been a top priority of drug abuse treatment researchers for years, there are still no approved medications to treat this disorder.

With the Buspirone for Relapse-Prevention in Adults with Cocaine Dependence study, researchers are testing whether buspirone is effective in preventing relapse in cocaine-dependent adults who are currently in inpatient or residential treatment, and who plan to enter outpatient treatment after discharge.

This double-blind study compares the effect of buspirone (active medication) to a placebo (inactive medication) to prevent relapse to cocaine use.

Who should apply?

You may be eligible for this study if you

- ❑ are 18 years of age or older.
- ❑ are enrolled in inpatient/residential treatment for cocaine.
- ❑ plan to enroll in outpatient treatment following your inpatient/residential treatment.

How long is the study?

If you complete the full study, you will be enrolled for approximately 4½ months (18 weeks). This includes a screening/baseline phase of up to 10 days, a 15-week study intervention phase (two visits per week), and one follow-up visit in week 16.

Screening/Baseline

- ❑ Approximately two research visits over 3-10 days, while still in inpatient/residential treatment.
- ❑ Assessments for medical, substance use, mental health, and general life history.
- ❑ Screening/baseline determines whether or not you are eligible to participate in the full study.

Active Treatment

- ❑ Randomly assigned to receive either buspirone or placebo. Neither you nor the study staff will know which medication you are assigned.
- ❑ Attend two study visits per week for 15 weeks to assess your medical and substance use status.

Follow-Up

- ❑ One visit 1 week after the end of the Active Treatment Phase.

What are the treatments?

If you complete all of the screening/baseline assessments and meet all requirements for the study, you will be randomly assigned (i.e., by chance, like flipping a coin) to receive either active medication (buspirone) or inactive medication (placebo).

Buspirone is a medication approved by the U.S. Food and Drug Administration for the treatment of generalized anxiety disorder; however, it is not approved as a treatment to prevent cocaine relapse.

Neither you nor the study staff will know what you are taking. In the event of an emergency, the study staff can find out whether you are taking buspirone or the placebo.

Will I be reimbursed?

Study participants will be reimbursed for their transportation, inconvenience, and time.

Is the study confidential?

Every effort will be made to keep your information private and confidential. A Certificate of Confidentiality has been obtained from the U.S. Department of Health and Human Services for this study.