



Uganda Russia Boston Alcohol Network for  
Alcohol Research Collaboration on HIV/AIDS

## **Zinc for HIV Disease among Alcohol Users – An RCT in the Russia ARCH Cohort** *Funded by the National Institute on Alcohol Abuse and Alcoholism (U01AA021989)*

This project is part of the Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS (URBAN ARCH) Consortium, a member of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) CHAART (Consortiums for HIV/AIDS and Alcohol Research Translation) initiative. URBAN ARCH conducts and disseminates interdisciplinary research aimed at understanding how alcohol use impacts people affected by HIV and develops interventions to reduce alcohol use and alcohol and HIV-related consequences in this population. Detailed information on the URBAN ARCH Consortium is available on our website, [www.urbanarch.org](http://www.urbanarch.org).

ZINC RCT aims to test the efficacy of zinc supplementation, compared to placebo, to:

- 1) Improve markers of mortality, as measured by the VACS index
- 2) Slow HIV disease progression, as measured by CD4 cell count
- 3) Improve markers of risk of acute myocardial infarction, as measured by the Reynolds risk score
- 4) Decrease microbial translocation and inflammation, as measured by serum biomarkers: IL-6, D-dimer, sCD-14, 16SrDNA

### **Study Design and Intervention**

- ZINC is a double-blind randomized placebo controlled trial with target enrollment of 250. It is nested with the Russia ARCH Cohort (U01AA020780).
- Participants are randomly assigned in a 1:1 ratio to zinc or placebo using balanced blocks stratified by gender and heavy alcohol consumption during the past week.
- Participants are invited to participate in four in-person interviews with blood collection at baseline, 6, 12, and 18 months, and four short medication visits at 6 weeks, 12 weeks, 9 months, and 15 months.
- Participants receive oral zinc/placebo over 18 months with instructions to take one pill daily.
  - Both zinc and placebo contain riboflavin (measure of adherence) and are identically packaged into bottles containing a 28-day supply.
  - Zinc pills for men and women contain 15 and 12 mg of active zinc gluconate, respectively.
- Adherence is measured directly through visual inspection of urine under ultraviolet light at each visit to monitor for color change due to riboflavin; and indirectly through pill counts and self-report.
- Participants are recruited from clinical care sites and non-governmental organizations serving HIV-infected persons in St. Petersburg, Russia. Recruitment into the trial began in October 2013.

### **Eligibility for ZINC RCT**

#### Inclusion Criteria:

- Documented HIV infection
- ART naïve at enrollment
- Heavy alcohol consumption\* in the past 30 days
- Age 18-70 years old
- Provision of information for two contacts to assist with follow-up
- Stable address within St. Petersburg or within 100 km
- Possession of a home or cell phone

\* Meets NIAAA criteria for at-risk drinking

#### Exclusion Criteria:

- Not fluent in Russian
- Cognitive impairment resulting in inability to provide informed consent

### Assessment Summary – ZINC RCT

Information collected	Study Time Point*	
	Baseline	Assessment at 6, 12, 18 months
<b>Administered Assessment</b>		
Demographics	X	X
HIV Testing and HCV Diagnosis	X	X
ART Use		X
ART Adherence VAS		X
Opportunistic Infections		X
Co-Morbidities	X	X
Brief Pain Inventory - SF	X	X
Medications	X	X
Zinc intake	X	X
HIV Symptom Index	X	X
International Personality Item Pool (IPIP) <sup>a</sup>	X	X
The Revised Life Orientation Test (LOT-R) <sup>a</sup>	X	X
Depressive Symptoms (CES-D) <sup>a</sup>	X	X
Tobacco Use (Fagerström)	X	X
Mini International Neuropsychiatric Interview (MINI) Alcohol <sup>b</sup>	X	
30-day Alcohol Timeline Followback (TLFB)	X	X
Alcohol Surrogates	X	X
Drug Use (modified RBS)	X	X
24 Hour Activities	X	X
Social Support Scale	X	X
Veterans Rand 12-Item Health Survey (VR-12) plus 4 cognitive questions from (MOS-HIV)	X	X
Adherence to Study Medication		X
Medication Satisfaction (TSQM)		X
Blinding Assessment		18 only
<b>Clinical and Laboratory Values</b>		
Height (m/cm)	X	X
Weight (kg)	X	X
Blood pressure (mmHg)	X	X
HIV Viral Load	X	X
CD4 count (calculated using CBC)	X	X
Hemoglobin and platelets	X	X
HCV Ab and HCV Ag (qualitative)	X	18 only
HS CRP	X	X
Cholesterol (total and HDL)	X	18 only
AST/ALT and creatinine	X	X
Zinc levels	X	18 only
Planned biomarker testing: sCD-14, IL-6, D-dimer, 16SrDNA	X	X
<b>Available Repository Samples</b>		
Plasma	X	X
DBS card	X	X

\*Adherence to study medication and ART use are assessed during short medication visits at 6, 12 weeks and 9, 15 months

<sup>a</sup> Self-administered

<sup>b</sup> Craving questions added in December 2013