



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

Alcohol & Zinc Impact on Inflammatory Markers in HIV Disease - Russia ARCH Cohort

Funded by the National Institute on Alcohol Abuse and Alcoholism (U01AA020780)

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.

Russia ARCH Cohort aims to:

- 1) Evaluate longitudinal association between alcohol consumption and biomarkers of microbial translocation (sCD14) and inflammation/altered coagulation (IL-6/D-dimer)
- 2) Establish a cohort of HIV-infected Russian drinkers
- 3) Establish a sample repository
- 4) Determine the association between alcohol consumption and HIV on biomarkers of adaptive immune dysfunction (CD4, CD8, CD57+, CD28-) – supplemental support

Study Design

- Russia ARCH is an observational cohort with an initial target enrollment of 250. The cohort will grow to up to 400 participants due to a nested randomized clinical trial, Zinc for HIV Disease among Alcohol Users – An RCT in the Russia ARCH Cohort (U01AA021989).
- The cohort aims to enroll a maximum of 125 participants with non-heavy alcohol use (past 30 days; NIAAA definition of risky drinking amounts: >14 standard drinks per week or > 4 drinks/day for men; > 7 drinks/week or >3 drinks/day for women.) The remainder of the participants will have heavy alcohol use (past 30 days) at baseline.
- Participants are invited to participate in three in-person interviews with blood collection at baseline, 12 and 24 months, and in two phone/brief interviews at 6 and 18 months.
- Participants are recruited from clinical care sites and non-governmental organizations serving HIV-infected persons in St. Petersburg, Russia.
- Recruitment for the Russia ARCH Cohort began in November 2012. The study reached its initial recruitment goal of 250 in October 2014.

Eligibility for Russia ARCH Cohort

Inclusion Criteria:

- Age 18-70 years old
- HIV-infected
- Provision of contact information for two contacts to assist with follow-up
- Stable address within St. Petersburg or districts within 100 kilometers of St. Petersburg
- Possession of a home or mobile phone
- ART naive at the time of enrollment

Exclusion Criteria:

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

Assessment Summary – Russia ARCH Cohort

Information collected	Study Time Point		
	Baseline	6 and 18 months (phone)	12 and 24 months
Administered Assessment			
Demographics	X		X
HIV Testing and HCV Diagnosis	X		X
ART Use		X	X
ART Adherence VAS			X
Opportunistic Infections			X
Health Care Utilization			X
Co-Morbidities	X		X
Brief Pain Inventory - SF	X		X
Medications	X		X
HIV Symptom Index	X		X
HIV Sex Risk Behaviors ^a	X		X
Sexual Partners ^a	X		X
HIV Risk Categories ^a	X		
HIV Stigma (abbrev. Berger scale) ^a	X		X
Depressive Symptoms (CES-D) ^a	X		X
Tobacco Use (Fagerström)	X	Q-1	X
Mini International Neuropsychiatric Interview (MINI) Alcohol ^b	X		X
Alcohol Use Disorders Identification Test (AUDIT)	X	X	X
Short Inventory of Problems (SIP) for alcohol use	X		Shortened
30-day Alcohol Timeline Followback (TLFB)	X		X
Mini International Neuropsychiatric Interview (MINI) Drug ^b	X		X
Drug Use (modified RBS)	X	Shortened	X
Household Food Insecurity Access Scale (HFIAS)	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	VR-12 Q-1	X
Clinical and Laboratory Values			
Height (m/cm)	X		X
Weight (kg)	X		X
Blood pressure (mmHg)	X		X
HIV Viral Load	X		At 12 only
CD4%	X		X
CD4 count (calculated using CBC)	X ^c		X
Markers of adaptive immunity (CD4,CD8, CD57+,CD28-) n=250	X		At 12 only
Planned testing pending receipt of funding: sCD-14, IL-6, D-dimer	X	X	X
Available Repository Samples			
Serum	X		X
Plasma	X		X
DBS card	X		X

^a Self-administered

^b Craving questions added in December 2013

^c Missing for first 103 participants

Russia ARCH

Study Team – Contact Information

Investigators

Jeffrey Samet, MD, MPH, MA
Principal Investigator, Russia ARCH
Principal Investigator, ZINC RCT
Principal Investigator, URBAN ARCH
Administrative Core
jsamet@bu.edu
Phone: 617.414.7288

Matthew Freiberg, MD, MSc
Co-Investigator, Russia ARCH
Principal Investigator, ZINC RCT
matthew.s.freiberg@vanderbilt.edu
Phone: 615.875.9729

Evgeny Krupitsky, MD, PhD, DMSci
Co-Investigator, Russia ARCH and ZINC RCT
Principal Investigator, Russian Subcontract
kruenator@gmail.com

Dmitry Lioznov, MD, PhD
Co-Investigator, Russia ARCH and ZINC RCT
dlioznov@yandex.ru

Elena Blokhina, MD, PhD
Co-Investigator, Russia ARCH and ZINC RCT
blokhinaelena@gmail.com

Edwin Zvartau, MD, PhD, DMsci
Co-Investigator, Russia ARCH and ZINC RCT
Zvartau@gmail.com

Biostatistics and Data Management

Debbie Cheng, ScD
Principal Investigator, BDM Core
Biostatistician, Russia ARCH and ZINC RCT
dmcheng@bu.edu
Phone: 617.638.5989

Michael Winter, MPH
Co-Investigator, Russia ARCH and ZINC RCT
mwinter@bu.edu
Phone: 617.638.5015

Greg Patts, MPH
Data Manager/Analyst, Russia ARCH
gpatts@bu.edu
Phone: 617.638.5029

Leah Forman
Statistical Programmer, Russia ARCH and ZINC RCT
lforman@bu.edu
Phone: 617.638.5017

Project Management

Carly Bridden, MA, MPH
Administrative Director, URBAN ARCH
Administrative Core
Carly.Bridden@bmc.org
Phone: 617.414.5768

Natalia Gnatienko, MPH
Project Manager, Russia ARCH and ZINC RCT
Natalia.Gnatienko@bmc.org
Phone: 617.414.3843

Project Coordinator

Sally Bendiks
Sally.Bendiks@bmc.org
Phone: 617.414.3802