

Title of Study: Returning Genetic Results on Arsenic Susceptibility to Bangladeshi Research Participants

NCT number: not yet assigned

Date of document: October 27 2020

Consent form (English version)

Title of Study: Assessing the Impact of Returning Genetic Results in a Bangladeshi Population

Objective:

This study is being carried out by Dr. Islam and his team at the University of Chicago Research Bangladesh (URB) office. The purpose of this research study is to assess the feasibility and benefits of returning genetic information to participants regarding their ability to remove arsenic from their body. This study examines the impact of returning genetic results on the amount of arsenic consumed in the future. Your urine samples will be obtained during your study visit. We will measure arsenic in the urine samples you provide. You are invited to participate because you are a member of the Health Effects of Arsenic Longitudinal Study (HEALS) cohort.

Procedures:

At baseline, participants will receive information regarding the effects of arsenic on health, and all participants will provide a urine sample for arsenic measurement. Participants will be asked to answer a few questions about your water sources and your understanding of genetics and health. At baseline, some participants (but not all) will receive their genetic results regarding arsenic metabolism. At a follow-up visit 6 months after baseline, another urine sample will be collected. Individuals who did not receive their genetic results at the baseline visit will have the opportunity to receive these results at the 6-month follow-up visit. At the end of the study, you will also be asked to answer a few questions regarding the psychological impact of receiving your genetic results. All urine samples will be stored at the University of Chicago.

Risks:

One potential risk is psychological stress caused by receiving the genetic information provided; however, a study physician will be available to you at your study visit to answer any questions you have and to minimize stress. There are no physical risks. There is a risk of loss of confidentiality, and we will minimize this risk by coding your samples and data so that no information that can be used to identify you. Data will be sent to the University of Chicago and stored on password-protected and secure servers. Our study team will maintain the coding between your samples and personal health information.

Benefits:

You will receive information regarding the effects of arsenic on your health as well as genetic information regarding your ability to metabolize arsenic. This information could help you reduce your exposure to arsenic and benefit your health. There are no other direct benefits to your participation in this study. There are no costs to you for participating.

Confidentiality:

All personal information provided will be handled in strictest confidence and in accordance with data protection laws. A unique study identification number has been assigned to you and will be used to label questionnaire and clinical information. By law, only authorized individuals may inspect these records.

Voluntary:

Participation in this study is voluntary. If you refuse to participate, this will involve no risk to you and no loss of benefits. Also, if you decide to participate in this study, you may stop your participation at any time.

Any questions:

If you have any questions or concerns about the study, you may contact Dr. Tariqul Islam of the UChicago Research Bangladesh at +88-xx-xxxxxxx or Dr. Habibul Ahsan of the University of Chicago at +1-773-824-9956. If you have any questions about your rights as a participant, you may contact Bangladesh Medical Research Council (BMRC), Mahakhali, Dhaka 1212, Bangladesh, Telephone: 8811395.