

Identifying biological markers of stress using proteomic analyses and correlating and validating these markers using psychosocial parameters evaluated during a treatment program for post traumatic stress disorder (PTSD) for tsunami victims in Sri Lanka

Japanese investigators who are currently studying biological markers of stress in populations in their own country wish to study such markers in persons who have recently suffered severe stress. They arrive in Sri Lanka as proceed to collect blood samples from tsunami victims but these samples are confiscated by the Chief Epidemiologist as they cannot provide evidence of ethics clearance. Subsequently they recruit local collaborators and submit an application for ethics clearance to a local ERC. They have clearance from their institutional ethics committee in the previous year but that does not cover collaborative research with a developing country.

The study will be conducted in the Matara district. The study design involves interviewing 3000 adult tsunami victims using five validated questionnaires to identify 300-600 persons with PTSD. The sample will be recruited by collaboration with the provincial medical officers of the district. Cognitive behavioral therapy (CBT) developed by one of the investigator combined with drug therapy will be administered to all patients. The CBT will be administered by trained Sri Lankan psychotherapists and psychiatrists. Both forms of therapy have known side effects. The Biological samples (blood, saliva and hair root samples) will be collected and psychological test conducted pre-treatment, post-treatment on patients and on a control group without PTSD. Comparisons of psychosocial factors, diagnosis and proteomic data will be conducted between subjects with and without PTSD and between subjects showing recovery from PTSD and those showing resistance to PTSD. The investigators state that the research will facilitate the identification of objective biomarkers for the diagnosis of PTSD that could also be predictors of later disease incidences and stress vulnerability and this would be an original finding that would be beneficial to medical science.

Informed consent forms for screening, therapy and sample collection are available in English. Participants will be paid a small monetary reward. Participants will be allowed to leave the study without forgoing participation in the treatment. Data collected will be anonymized at the point of collection.

The investigators state that the tsunami victims will benefit by being diagnosed and treated using a treatment package of well-established efficacy and that the intellectual property rights will be beneficial to both sets of researchers.