

## **SLCTR/2008/017 - Zinc status in patients with diabetes mellitus and efficacy of multi mineral supplementation on glycaemic control with special reference to zinc**

Progress report 1- Submitted date: 5<sup>th</sup> March 2009

### **Preliminary actions**

The research study was registered with Sri Lanka clinical Trials Registry on 22nd August 2008. Then the manufacturing of multi-minerals (two preparations with or without zinc) and the placebo tablets were started at the Apex laboratories, India through its local agent A. Baur & Co Ltd under the license granted by the Drug Regulation Authority (DRA) of the Ministry of Health, Sri Lanka.

### **Subject recruitment**

This was commenced on 1st December 2008. Diabetic patients who were on follow-up more than a year at the Medical Clinics of the Teaching Hospital, Karapitiya were invited to the study. Those who were consented were requested to come for the baseline assessment on blood sugar, dietary intake and physical activity at the Nuclear Medicine Unit of the Faculty of Medicine. After this, they were randomly assigned to three groups. Group A was given multi mineral tablets, Group B subjects were given the multi mineral tablet without zinc and Group C was assigned to the placebo supplementation. None of the study subjects were aware of the group (single blind study) and they were instructed to consume the tablets once a day with other medications. Further, if any one experienced with new problems (side effects like skin rash) were requested to report to the researcher immediately. So far all the subjects (n=32) are followed up at their respective clinics. Subjects for the control group were recruited in February 2009.

### **Results generated**

Dietary survey data are being processed. Physical activity assessment has been done in the supplementation group. Blood samples obtained so far have been tested for sugar (Fasting and post prandial), haemoglobin A1C, lipids and insulin.

### **Publications**

Not done.