CICLO CARLOS CHAGAS DE PALESTRAS

6ª EDIÇÃO

110 anos da descoberta do *Trypanosoma cruzi*

LIVRO DE RESUMOS

IOC Instituto Oswaldo Cruz
Ministério da Saúde
FIOCRUZ Fundação Oswaldo Cruz
MINISTÉRIO DA SAÚDE
BRASIL PÁTRIA EDUCADORA

Terapias (imunoterapia, terapia celular e outras)
Therapies (immunotherapy, cellular therapy and others)

Selenium treatment and Chagasic cardiopathy (STCC) clinical trial: first results on selenium levels at baseline

Tania C. Araújo-Jorge [a *], Beatriz M.S. Gonzaga [a], Fernanda Sant'ana P. Silva [a], Anna Cristina C. Carvalho [a], Luciana R. Garzoni [a], Sérgio S. Xavier [b], Gilberto M. Sperandio da Silva [b], Roberto M. Saraiva [b], Andrea S. de Sousa [b], Paula Simplício da Silva [b], Luiz Henrique C. Sangenis [b], Alejandro M. Hasslocher-Moreno[b], Marcelo Teixeira de Holanda [b], Pedro E.A.A. Brasil [b], Mauro Felippe Felix Mediano [b]

[a] Laboratory of Innovations in Therapies, Education and Bioproducts, Institute Oswaldo Cruz (LITEB-IOC/Fiocruz), Oswaldo Cruz Foundation (Fiocruz), Rio de Janeiro.
[b] Laboratory of Clinical Research in Chagas disease, Evandro Chagas National Institute of Infectious Diseases (INI/Fiocruz), Oswaldo Cruz Foundation (Fiocruz), Rio de Janeiro.
E-mail: anna.carvalho@ioc.fiocruz.br, biagonzaga04@hotmail.com

Background: patients with cardiac form of CD have lower selenium (Se) levels than both healthy individuals and patients with *T. cruzi* infection without heart disease. Supplementation with Se in an animal model for CD produced promising results. A "Selenium Treatment and Chagasic Cardiopathy" trial is ongoing.
Objective: to describe the plasma levels of Se in patients with mild and moderate chagasic cardiopathy and their association with left ventricular systolic dysfunction, in patients recruited in STCC, and to better specify the hypothesis of Se role in Chagas disease. The trial is a superiority, double-blinded, placebo-controlled, randomized clinical trial aiming to estimate the effect of Se treatment on prevention of heart disease progression in patients with CD cardiac form. CD patients aging 18 to 75 years-old with normal/segmental, mild or moderate global left ventricular systolic dysfunction (evaluated by left ventricular ejection fraction – LVEF) were included in the STCC trial. Median (25^{th}-75^{th}) values of Se were described. Pearson correlation coefficient (PCC) between Se plasma levels and LVEF percentages was calculated. The association between Se plasma levels and LVEF classes was evaluated using nonparametric Kruskal-Wallis test. **Results**: data from 47 participants (75% of calculated trial sample) were included in this analysis. Median (25^{th}-75^{th}) Se levels at baseline were, 82 mcg/L for both women and men (71-99 for all, 64-99 for women, 78-105 for men). According to baseline Se levels, 10 patients were classified as low Se (40-64 mcg/L, 8 women, 2 men), 26 patients with sufficient Se (65-99 mcg/L, 15 women, 11 men) and 11 patients with ideal Se concentrations (100-152 mcg/L, 6 women, 5 men). There was no statistically significant association between trace elements and LVEF classes. PCC between Se plasma levels and LVEF was 0.11. **Comments**: we did not identify an association between Se levels and left ventricular systolic dysfunction in CD patients at enrollment. However, one-fifth of patients (21.3%; 10/47) were in the lower selenium level range at baseline. Since blind code will be broken only after 1-year follow-up of the last patient enrolled in the trial, we cannot conclude now if there is any correlation between outcome and the initial range of trace elements plasma levels. The hypothesis is that the lower Se group will have a higher risk of pathology evolution. If this hypothesis is confirmed, the inclusion of this micronutrient in the daily diet will improve the therapeutic regimen for this neglected tropical disease at low cost.
Acknowledgements: this work was supported by the governmental agencies CNPq, CAPES, FAPERJ, the Research Vice-Presidency of Fiocruz and the Department of the Industrial Complex and Innovation in Health from the Brazilian Health Ministry. Trial registration: STCC; Trials 6;15:388, 2014; Clinical Trials ID: NCT00875173.