

Effect of ingestion of mate tea and chocolate in the endothelium of individuals with HIV / AIDS.

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If the intervention with mate tea and cocoa in individuals with HIV on HAART can improve the cardiovascular risk profile to prevent or reduce high blood concentrations of inflammatory markers, lipoproteins (LDL, VLDL) and triglyceride levels, reduce...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28657

Bron

Nationaal Trial Register

Verkorte titel

Chocolate and Mate tea in patients with HIV

Aandoening

HIV and HAART.

Key words: Endothelium, HIV / AIDS, Antiretroviral Therapy High Power, cocoa, tea, mate.
Endotheel, HIV / AIDS, antiretrovirale therapie High Power, cacao, thee, mate.

Ondersteuning

Primaire sponsor: University of Sao Paulo - School of Public Health - Brazil

Overige ondersteuning: State of Sao Paulo Research Foundation (FAPESP) Brazil

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Assessing the impact of eating chocolate and mate tea on endothelial function and vascular elasticity of patients with HIV / AIDS.

Toelichting onderzoek

Achtergrond van het onderzoek

There is growing interest in identifying markers for risk of cardiovascular events in HIV/AIDS infected patients. Studies demonstrate that patients being treated with antiretroviral therapy for high-power (HAART) show high concentrations in markers of activation of the endothelium. Epidemiological studies suggest benefits of cocoa on human health accumulating evidence that some forms of cocoa and chocolate rich in flavonoids improve cardiovascular function by improving endothelial function. In the same way, clinical studies with mate tea have shown positive vasodilators biological effects. Objective: Evaluate the impact of ingestion of mate tea and chocolate in the endothelium of individuals with HIV/AIDS. Methodology: Randomized, placebo-controlled, single-blind crossover trial of 180 volunteer's patient of HIV/AIDS clinic specializing, aged 19 and 49 years, in ART treatment for at least six months. Individuals will be supplemented for 105 days (washout of 15 days) with 75g of chocolate bar (containing 36g cocoa powder) and 200mL of mate tea, prepared as required by the manufacturer. They will be checked markers anthropometric, biochemical, immunological and inflammatory, and will be measured elasticity of large and small arteries and pulse-wave velocity.

Categorical variables are described with the number of individuals and percentage of each category. ANOVA will be used to assess differences in responses between intra-individual treatments on the variables of interest. The paired sample test will be used to compare baseline values of all variables, before and after supplementation.

Excel 2011 for Windows will be used for information storage. Data will be analyzed with the software Statistical Package for Social Sciences (SPSS) version 13.0 for Windows and Stata version 11.0. $p < 0.05$.

Doel van het onderzoek

If the intervention with mate tea and cocoa in individuals with HIV on HAART can improve the cardiovascular risk profile to prevent or reduce high blood concentrations of inflammatory markers, lipoproteins (LDL, VLDL) and triglyceride levels, reduce oxidative stress, promoting improvement of endothelium and vessel elasticity.

Onderzoeksopzet

Baseline, 15days, 45 days, 75 days and 105 days.

Onderzoeksproduct en/of interventie

Individuals are supplemented with 65g chocolate bars containing cocoa 36g and 300 mL of mate tea. As placebo tablets were formulated without cocoa and 300 mL of prepared liquid with similar appearance and aroma to the mate tea.

The whole intervention period is 105 days divided into four phases, each of which lasts 15 days, followed by a washout in the same time. In phase I, 180 subjects were randomized to ensure the receipt of one of four possible supplementation in phase II will be held in rotation supplementation, the same occurring in stages III and IV, thus ensuring that all volunteers participate in the four treatments.

Supplementation is daily and membership is confirmed by personal contact or telephone.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Individuals of both sexes aged 19 to 59 years with HIV / AIDS and who were on regular treatment with HAART for at least six months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Individuals who had at least one of the following criteria:

History of myocardial infarction or stroke, cardiac arrhythmia, Chagas disease, heart failure, in lipid-lowering medication use, weight greater than 150kg, diabetes mellitus, hypertension, renal disease (creatinine > 2.0 mg / dL), severe intestinal disease that prevents the use of diet, hypothyroidism (TSH > 6.0 IU / mL), liver failure, malignant neoplasm, active opportunistic infection at the time, pregnancy, chronic alcoholism, vegetarian diet ; other individuals participating in research, and supplements or intolerance to any of its components.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	05-05-2011
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	05-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3028
NTR-old	NTR3176
Ander register	: 2009/52250-5
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A