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Miami Selenium for heart & immune health trial

Submission date	Recruitment status	[_] Prospectively registered
13/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/08/2011	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RO1 DA13128

Study information

Scientific Title

Acronym
MIASEL

Study objectives
The primary aim of this project is to examine whether selenium supplementation in cocaine-abusing and non-substance-abusing Human Immunodeficiency Virus (HIV) infected persons will diminish oxidative stress and improve immune function, insulin sensitivity, cardiac and vascular function, and indices of Cardiovascular Disease (CVD) risk. The secondary aim of this project is to determine whether oxidative stress, insulin sensitivity, and immune and cardiovascular function are potential mediating mechanisms for selenium effects on the measures of CVD risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
3/23/2001; 5/15/2002; 4/14/2003; 3/8/2004; 3/29/2005; 1/18/2006 WIRB PRNo:20060171
All dates except the last pertain to University of Miami Institutional Review Board. Due to institutional difficulties, the protocol was then outsourced by the University of Miami to the Western Institutional Review Board.

Study design
Two group randomised double-blind placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Human Immunodeficiency Virus (HIV)

Interventions
Selenium supplement (200 ug/day) versus placebo

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Selenium

Primary outcome measure
HIV viral load, CD4 count, metabolic syndrome, cardiac contractility, cardiac compliance, cardiac mass

Secondary outcome measures
Oxidative stress, inflammation

Overall study start date
23/03/2001

Completion date
30/06/2006

Eligibility

Key inclusion criteria
1. Participants provided informed consent
2. Presented documented evidence of their HIV-1 infection
3. Were 18 to 55 years of age
4. Were not being treated pharmacologically for a diagnosed cardiovascular condition (e.g., beta-blockers, calcium antagonists, Angiotensin-Converting Enzyme [ACE] inhibitors), for carbohydrate conditions (e.g., hypoglycemics, insulin sensitizers), for psychiatric conditions (e.g., antipsychotics, antidepressives), and for endocrine conditions (e.g., estrogen hormonal replacement)
5. Presented no evidence of myocardial infarction or Atrio-Ventricular (AV) conduction arrhythmias upon electrocardiogram
6. Had no history of diabetes or cardiovascular disorder, or other major systemic diagnosis unrelated to HIV spectrum disease
7. Had no gross neurocognitive dysfunction indicated by a Folstein Mini-Mental Status Exam (MMSE) score < 26
8. Did not have a recent acute infection or surgery within three months of study entry
9. Were premenopausal and not pregnant with no intent to become pregnant
10. Were not participating in another blinded clinical trial
11. Refused to discontinue use of a nutritive supplement that contained > 50 ug per pill
12. Had a serum selenium level upon screen equal or superior to 75 ug/l.

Participants meeting these criteria signed an informed consent form for screening and if still eligible additional written consent was obtained for randomization into the trial.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
280

Key exclusion criteria
1. Participating in another blinded clinical trial
2. Being treated pharmacologically (e.g., beta-blockers, calcium antagonists, ace inhibitors) for diagnosed cardiovascular function
3. Pregnant or have the intent to become pregnant
4. Post-menopausal women
5. Presenting an electrocardiogram (ECG) arrhythmia in which the proposed cardiovascular assessments would be contraindicated
6. Taking any medications that have contraindicating cardiovascular effects (i.e., tricyclic anti-depressant medications, etc.)
7. Displaying gross neurocognitive dysfunction indicated by a Folstein Mini-Mental Status Exam (MMSE) score equal or superior to 26

Date of first enrolment
23/03/2001

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
United States of America

Study participating centre
Behavioral Medicine Reaserch Center (200 BMRC)
Miami
United States of America
33125

Sponsor information

Organisation
National Institute on Drug Abuse (USA)

Sponsor details

National Institutes of Health
6001 Executive Boulevard
Room 5213
Bethesda
United States of America
20892-9561
+1 301 443 1124
webmaster@lists.nida.nih.gov

Sponsor type
Government

Website
http://www.nida.nih.gov

ROR
https://ror.org/00fq5cm18

Funder(s)

Funder type
Government

Funder Name
National Institute on Drug Abuse (USA)

Alternative Name(s)
Instituto Nacional sobre el Abuso de Drogas de Estados Unidos, Instituto Nacional sobre el Abuso de Drogas, NIDA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	22/01/2007		Yes	No