

CEP'S CONSUBSTANCED OPINION

DATA ABOUT THE RESEARCH PROJECT

Research Title: Metal Detection in Biospecimens from Children of Recyclable Waste Pickers living in Brasília- Brazil

Researcher: VANESSA RESENDE NOGUEIRA CRUVINEL

Thematic field:

Version: 4

CAAE: 91318718.5.0000.8093

Proponent Institution: POSTGRADUATE PROGRAM IN SCIENCES AND TECHNOLOGIES IN

Main Sponsor: Internal financing

OPINION DATA

Opinion number: 2.871.509

Project presentation:

Environmental exposure to lead is one of the most relevant public health issues, since contamination of children in their first months and years of life can trigger severe neurological and behavioral disorders. Millions of people worldwide have been contaminated with lead and the adverse effects of such contamination on human health have been scientifically proven, fact that made it a public health issue. Several lead biomarkers such as blood, plasma, bone, saliva, hair, nail, urine, feces and teeth have been cited in the literature; however, each biomarker can present varying validity and reveal a specific condition. An analytical cohort comprising 204 children in the age group 6-12 years will be assessed. Of this total, 102 individuals will be the children of recyclable waste pickers living in Estrutural County (lead-contaminated region), Federal District (G1), whereas 102 will be the children of non-waste pickers living in Ceilândia neighborhood (area where the water is not contaminated, as reported by ADASA - Federal District Water, Energy and Basic Sanitation Regulatory Agency) (G2). The aim of the study is to identify the presence of lead (Pb) and other metals in biospecimens, such as teeth and saliva, collected from these children. A questionnaire concerning general data such as place of residence, family income, child's age, overall health issues, among others, will be applied to participants after they sign the Free and Informed Consent Term. Subsequently, children's teeth will be examined in order to identify carious lesions, teeth undergoing exfoliation and structural defects in the dental enamel.

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After this procedure is over, oral education and hygiene lectures will be given to all children and families. Children presenting dental issues will be properly instructed and invited to undergo free dental treatment. Teeth diagnosed with carious lesions will be restored with Riva STAR glass ionomer cement manufactured by SDI. Caregivers and children will be asked to donate exfoliated deciduous teeth. The amount of metals will be determined through graphite furnace atomic absorption spectroscopy. Stimulated saliva will be collected from all the 204 children. Mann Whitney's nonparametric test will be used to compare metal concentrations in children's saliva and teeth; significance level 0.05 will be adopted in the statistical analysis, which will be performed in the Epidata[®] software. Children of recyclable waste pickers living in the area known to be contaminated with lead are expected to present higher concentrations of this metal in their teeth and saliva than children of non-waste pickers living in the non-contaminated region.

Research aims:

Primary aim: identifying Pb (lead) in the exfoliated teeth of the examined children; identifying Pb (lead) and other metals in the saliva of the examined children.

Secondary aim:

Comparing heavy metal concentrations in different dental enamel layers, and in the primary and secondary dentins of exfoliated deciduous teeth, in children living in Federal District regions with different environmental pollution records;

Investigating whether there is significant difference between the amount of heavy metals found in the teeth of children living in different Federal District regions;

Investigating whether there is significant difference between the amount of lead found in the saliva of children living in different Federal District regions;

Comparing groups based on EDD (Enamel Development Defect) and Pb (lead) contamination;

Investigating the prevalence of enamel defects in the studied population, as well as the history of systemic diseases and their association with heavy metals.

Risk and Benefit Assessment:

Risks: The confidentiality of all collected data will be assured. Appropriate treatment and behavior management techniques will be adopted to minimize any discomfort resulting from possible unpleasant reactions to the dental treatment. A rubber material will be given to the children, who will chew it to stimulate saliva production in order to enable its collection. A piece of dental floss will be tied to the rubber material, so we can pull it out if the child swallows it.

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BENEFITS: Dental treatment will be applied to children diagnosed with structural defects in the dental enamel; All children will receive oral hygiene and diet instructions, as well as a kit containing toothbrush, toothpaste and dental floss;

Children presenting Pb (lead) concentrations above the permitted limit will be clarified about their condition.

Comments and Research Considerations:

This is a master's (or doctoral) research project coordinated by Vanessa Resende Nogueira Cruvinel, Ana Cristina Barreto Bezerra, Danuze Batista Lamas Gravina and Eliude Barbosa Gomes; it will be carried out within the FCE/UnB scope in partnership with the Urban Cleaning Service of DF. The total sample will comprise 204 children in the age group 6-12 years. Of this total, 102 individuals will be the children of recyclable waste pickers living in Estrutural County (lead-contaminated region), Federal District (G1). The other 102 individuals will be the children of non-waste pickers living in a non-contaminated area of the Federal District (G2). The sample will be formed based on drawing lots.

Considerations Regarding Mandatory Filing Terms:

All documents were properly presented.

Conclusions, Pending Matters and List of Inadequacies:

No pending matters.

Final Considerations at CEP's discretion:

The research protocol is in compliance with National Health Council Resolution 466/12. It should be emphasized that the researcher in charge is responsible for developing the project as it was outlined, preparing and submitting partial and final reports, submitting data required by CEP or CONEP at any time, keeping research data on physical, or digital, file under his/her custody and responsibility for 5 years after the end of the research, submitting research results for publication by giving the due credit to associated researchers and technical staff members of the project, and justifying before CEP or CONEP, on solid basis, any interruption in the project or failure to publish the results.

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This opinion was based on the documents listed below:

Document type	File	Posted on	Author	Status
Basic information about the project	PB_INFORMAÇÕES_BASICAS_DO_P ROJETO_1115582.pdf	08/20/2018 7:12:22 p.m.		Accepted
Detailed project/ Brochure Investigator	Projeto_COMPLETO_CEP_BIOESPECI MES.docx	08/20/2018 7:11:30p.m	DANUZE BATISTA LAMAS GRAVINA	Accepted
Others	cartapendencias2008.pdf	20/08/2018 7:09:38 p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Others	cartapendenciacep.pdf	08/15/2018 11:08:30 p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
FICT / Terms of Assent / Absence Justification	TCLEFEPECSFCE.docx	08/15/2018 10:59:21p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
FICT / Terms of Assent / Absence Justification	termo_de_assentimento.doc	08/15/2018 10:23:11p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Others	cartarespostapendencia3.jpeg	07/23/2018 9:12:19 p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Others	cartarespostaapendencia.pdf	07/12/2018 5:43:39 p.m.	VANESSA RESENDE NOGUEIRA	Accepted
Others	respostaapendencias.pdf	07/06/2018 9:18:59 p.m.	VANESSA RESENDE NOGUEIRA	Accepted
Others	termoconcordanciafce.pdf	06/06/2018 5:53:05 p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Declaration of Institution and Infrastructure	instcoparticipanteportugues.pdf	06/06/2018 8:52:30 a.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Others	cartaencaminhamento.jpg	06/04/2018 2:37:45 p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Others	termocoparticipacao slu.jpg	06/03/2018 5:28:04 p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Others	termocompromissopesquisador.pdf	06/03/2018 5:26:37 p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Others	termocoparticipacaoSES.jpg	06/03/2018 5:24:54 p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted

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Budget	orcamento.pdf	06/03/2018 10:23:27 a.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Schedule	Cronograma.pdf	06/03/2018 10:21:02 a.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Title page	folhaderosto.pdf	06/01/2018 2:02:22 p.m.	DANUZE BATISTA LAMAS GRAVINA	Accepted
Others	Curriculo_Lattes_Ana_Cristina_Barreto_ Bezerra.pdf	05/09/2018 1:53:47 p.m.	ELIUDE BARBOSA GOMES	Accepted
Others	Curriculo_Lattes_Vanessa_Resende_No gueira_Cruvinel.pdf	05/09/2018 00:38:09 a.m.	ELIUDE BARBOSA GOMES	Accepted
Others	Curriculo_Lattes_Eliude_Barbosa_Gome s.pdf	05/09/2018 00:37:18 a.m.	ELIUDE BARBOSA GOMES	Accepted
Others	Curriculo_Lattes_Danuze_Batista_Lama s_Gravina.pdf	05/09/2018 00:36:31a.m.	ELIUDE BARBOSA GOMES	Accepted
Others	Termo_concessao_dentes.docx	05/09/2018 00:31:18 a.m.	ELIUDE BARBOSA GOMES	Accepted
Declaration of Institution and Infrastructure	Declaracao_de_infraestrutura.docx	05/09/2018 00:29:07 a.m.	ELIUDE BARBOSA GOMES	Accepted
Declaration of Institution and Infrastructure	Declaracao_de_infraestrutura.jpg	05/09/2018 00:28:52 a.m.	ELIUDE BARBOSA GOMES	Accepted

Opinion Status:

Approved

Pending CONEP assessment:

No

BRASÍLIA, September 4, 2018

Signed by:
Dayani Galato
(Coordinator)

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