
Informed consent

Influence of treatment of periodontal disease on sirtuin 1 and mannose-binding lectin in individuals with coronary artery disease

This study was carried out in the Clinical Department, Heart Institute (InCor), University of São Paulo Medical School, São Paulo, Brazil. And Division of Periodontology, Stomatology Department, Dental School, University of São Paulo, São Paulo, Brazil.

This study is the result of a doctoral thesis presented at the Faculty of Medicine of the University of São Paulo (2016- Nov.2018).

Advisor: Prof. Dr. Antonio de Pádua Mansur

São Paulo, 06 october 2016

The present study does not have NCT

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OF MEDICINE - HCFMUSP

INFORMED CONSENT

RESEARCH SUBJECT IDENTIFICATION

NAME:
ID N° : GENDER : .M F
DATE OF BIRTH:/...../.....
ADDRESS.....
CITY/ZIP CODE
PHONE: ().....().....

DATA RESEARCH

1. TITLE OF RESEARCH PROTOCOL: Influence of treatment of periodontal disease in sirtuin 1 and Mannose-binding lectin in individuals with coronary artery disease.

2. NAME OF PRINCIPAL INVESTIGATOR: PhD. Antônio Pádua Mansur
TITLE / POSITION: Associate Professor

REGISTRATION REGIONAL COUNCIL: CRM N° 40.212

NAME OF ORGANIZATION: INCOR- Coronary artery unit in partnership with the Faculty of Dentistry of the University of São Paulo (FOUSP)

NAME OF ASSISTENT INVESTIGATOR: Pérola Michelle Vasconcelos Caribé

REGISTRATION REGIONAL COUNCIL: CRO n° 104.900

3. RESEARCH RISK ASSESSMENT:

MINIMUM RISK X MEDIUM RISK
LOW RISK GREATER RISK

4. RESEARCH DURATION: 24 months

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You are being invited to participate in a research project that consists of analyzing the influence of the treatment of periodontal disease, which is a disease that affects the supporting structures of the teeth, in atherosclerotic disease, which is an obstruction of blood vessels. We will also analyze the influence of this treatment on a group of proteins present in our body called sirtuins and mannose binding protein.

The purpose of this research is that this knowledge contributes in the future to better conduct in the treatment and / or prevention of these diseases. So the greater benefit is not straightforward for you. To perform this research you will participate in an initial dental consultation, where an interview will be conducted followed by an intra-oral clinical examination, in which the structures that support your teeth will be evaluated and the presence / absence of periodontal disease will be investigated. If you have periodontal disease you will receive treatment at the Periodontology Clinic of the School of Dentistry of the University of São Paulo (FOUSP) until there is control and / or elimination of the disease. Blood collection will also be performed by peripheral puncture of the forearm vein to perform the laboratory tests at the beginning and at the end of the study. This collection will be performed before and after the treatment of periodontal disease.

This research offers minimum predictable risks, such as: discomfort when spending time with the mouth open for the intra-buccal examination and for the treatment and puncture of the blood sample can feel pain, feeling faint and bruises in the blood withdrawal site. Your participation in the study is voluntary and you may withdraw from the study at any time. The freedom to withdraw consent is guaranteed at any time and to cease to participate in the study, without prejudice to the continuity of its treatment in the institutions. At any stage of the study, you will have access to the professionals responsible for the research to clarify any doubts. The information obtained in the study will be analyzed together with other patients, and the identification of no patients will not be disclosed. The results of this study may be presented at scientific meetings and publications, however, their identity will be kept confidential. The data and collected material will be used only for this research.

There are no personal expenses for the participant at any stage of the study, including examinations and consultations. There is also no financial compensation related to your participation. If there is any additional expense, it will be absorbed by the research budget. This term will be signed in two copies and you will receive one of the original copies. The investigators of the study are PhD. Md. Antonio de Padua Mansur and Pérola Michelle Vasconcelos Caribé that can be found at the Heart Institute (InCor) at (11) 2661-5387. And Dr. Giuseppe Alexandre Romito that can be found in the periodontics department of the School of Dentistry of USP (FOUSP) at (11) 3091-7822. If you have any questions or concerns about the research ethics, please contact the Research Ethics Committee (CEP) - Rua Ovídio Pires de Campos, 225 - PHONE: 2661-6442 Extensions 16, 17, 18 - E-mail: marcia.carvalho@hc.fm.usp.br

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I believe I have been sufficiently informed about the information I read or have read to me describing the study Influence of periodontal and atherosclerotic disease on the sirtuin and mannose binding protein system.

I discussed with Dr. Antonio P. Mansur and / or Pérola Michelle Vasconcelos Caribé about my decision to participate in this study. It was clear to me what the purposes of the study were, the procedures to be carried out, their discomforts and risks, the guarantees of confidentiality and permanent clarification. It is also clear that my participation is free of expenses and that I have guaranteed access to hospital treatment when necessary. I voluntarily agree to participate in this study and may withdraw my consent at any time, before or during it, without penalty or loss or loss of any benefit I may have acquired, or in my attendance at this Service.

Signature of Participant

Date: ___ / ___ / ___.

(Only for the person in charge of the project)

I declare that I have obtained in an appropriate and voluntary manner the Free and Informed Consent of this patient or legal representative for participation in this study.

Signature of Investigator

Date: ___ / ___ / ___.