HOSPITAL DAS CLÍNICAS DA FACULDADE DE MEDICINA DA UNIVERSIDADE DE SÃO PAULO-HCFMUSP

INFORMED CONSENT

RESEARCH DATA

Official Title: Expanded Hemodialysis Versus Online Hemodiafiltration: a Pilot Study on Intradialytic Hemodynamics and Fluid Status

NCT ID NCT03274518

Unique Protocol ID: 16928

Document Date: 10/17/2018

Main Investigator: Bruno Caldin da Silva

Institution: University of São Paulo, School of Medicine

INVITATION

We invite you to participate in this research protocol to be performed at the hemodialysis service of Hospital das Clínicas / University of São Paulo.

BACKGROUND AND OBJECTIVES OF THE STUDY

This study aims to find out if expanded hemodialysis is not inferior to online hemodiafiltration. Some studies show that online hemodiafiltration is superior to conventional hemodialysis by increasing the removal of some toxins and reducing episodes of hypotension. There are no studies that compared online hemodiafiltration with this new modality of dialysis, called expanded hemodialysis.

PROCEDURES AND OBJECTIVES OF THE STUDY

The Research involves converting your conventional hemodialysis method to online hemodiafiltration or expanded hemodialysis for 1 month. In the first and last session, you will perform blood collection (as in the "routine exams") and perform two additional tests: an electrical bioimpedance and cardiac evaluation by the "Finometer" device. These last two tests are non-invasive and do not cause any type of pain or discomfort. At the end of the first month, you will return to your standard hemodialysis for 15 days. Afterwards, the patient who underwent online hemodiafiltration in the first month will undergo expanded hemodialysis for another month. If you have had expanded hemodialysis, you will have hemodiafiltration online. The same exams will be done at the beginning and end of the month.

Nothing will change in your dialysis routine. Your shift, your entry and exit times will follow the same rules. The only difference will be the type of dialyzer used (in the case of expanded hemodialysis) or the conversion to online hemodiafiltration. Nothing will change in relation to your current dialysis, including medications, physician assistant etc.

For Bioimpedance assessment, some wires will be placed on your fingers and ankles. This exam takes only a few minutes to complete.

For heart evaluation, a sensor will be placed on your finger for 10 minutes immediately before and after the start of your dialysis session.

EXPLANATION OF POSSIBLE DISCUSSIONS AND RISKS ARISING FROM INVESTIGATION IN RESEARCH

There will be no discomfort or risk regarding dialysis methods.

For the evaluation of the heart, the sensor will cause a slight compression on your finger, which, however, does not cause pain. Electrical bioimpedance does not cause pain or discomfort.

EXPECTED BENEFITS FOR THE PARTICIPANT

There is no direct benefit to the participant. Eventually, online hemodiafiltration may cause fewer episodes of hypotension than conventional hemodialysis.

GUARANTEES OF FULL FREEDOM FROM THE PARTICIPANT TO REFUSE TO PARTICIPATE OR WITHDRAW THE TERMS OF CONSENT AT ANY PHASE OF THE RESEARCH WITHOUT ANY PENALTY, SECURITY AND PRIVACY.

This research will not change the procedure of your hemodialysis. There is no alternative procedure. You can however choose not to be part of the research. 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 Institution

COPY OF INFORMED CONSENT

One copy of this consent form will remain with you.

EXPLANATION OF THE WARRANTIES OF RESULTS FOR EXPENSES ARISING OUT OF THE RESEARCH AND EXPLANATION OF THE GUARANTEE OF INDEMNIFICATION FOR ANY DAMAGES ARISING OUT OF THE RESEARCH

This is a minimum risk research. There is no possibility of any damages by the exchange of the method (from conventional hemodialysis to online hemodiafiltration or expanded hemodialysis). The risks associated with the procedure are the same (or even lower) than conventional hemodialysis. 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.

The information obtained will be analyzed altogether with other patients. There will be no patient identification after study completion.

At any stage of the study, you will have access to the professionals responsible for the research to clarify any doubts. The main researcher is Dr Bruno Caldin da Silva, who can be found at Rua Enéas de Cravalho Aguiar 155, Cerqueira Cesar. Telephone number 2661-7167. If you have any questions or concerns about the research ethics, please contact the Research Ethics Committee (CEP) - Rua Ovídio Pires de Campos, 225 - 5º andar - tel: (11) 2661-7585, (11) 2661-1548, (11) 2661-1549; E-mail: cappesq.adm@hc.fm.usp.br.

I was sufficiently informed about the study " Expanded Hemodialysis Versus Online Hemodiafiltration: a Pilot Study on Intradialytic Hemodynamics and Fluid Status ".
I discussed with the nurse Paola da Ponte Silva or Dr. Bruno Caldin da Silva about my decision to participate in this study. The objectives, the procedures, the potential discomforts and risks and the guarantees were clear to me. I voluntarily agree to participate in this study and sign this informed written consent. I also have a copy of this consent.

Signature of patient / legal representative Date ___/___/___

Sinature of study investigator Date ___/___/___
