Timing of intradialytic exercise and its impact on intradialytic hypotension: a randomized crossover study

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: Timing of intradialytic exercise and its impact on intradialytic hypotension: a randomized crossover study

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You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your friends, family or (if applicable) your doctor before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information you do not clearly understand.

Conflict of Interest

Dr. Clara Bohm is receiving funds from the University of Manitoba Department of Internal Medicine to conduct this study.

Purpose of the Study

This research is being conducted to look at whether there is a difference in the occurrence of low blood pressure events during hemodialysis when individuals cycle during hemodialysis in the first half of hemodialysis sessions as compared to cycling during the second half of hemodialysis sessions. You are being asked to participate in this study because you participate in the Manitoba Renal Program's Intradialytic Cycling Program. A total of 90 participants (30 at each site) will participate in this study at 3 sites across Canada (Winnipeg, Calgary and Edmonton). The purpose of this research is to see whether performing exercise during the second half of hemodialysis increases the number of low blood pressure events people experience during hemodialysis. There has been no research specifically addressing the effect of exercise in the second half of hemodialysis sessions. Most programs have people exercise during the first half of hemodialysis. We are studying this because, allowing exercise during the second half of hemodialysis would allow for a more flexible intradialytic exercise schedule for hemodialysis patients and may improve symptoms of cramping and restless legs that are more likely to occur in the second half of hemodialysis.

Study Procedures

This will be a 4-week study. During this study you will cycle during your hemodialysis sessions as usual, only the timing of the cycling will change. How long you cycle and how hard you work when you are cycling will not change from your current program. You will be randomly assigned to one of 2 groups. Group 1 will start with 2 weeks of cycling in the first half of their hemodialysis session (as is standard in the hemodialysis unit) and then will cycle in the second half of their hemodialysis session for the next 2 weeks. The cycling schedule for Group 2 will be the reverse order of Group 1. Regardless of group, your blood pressure will be measured every 15 minutes while you are on HD during the study. At the end of each study assessment, you will be asked about your recovery time after your last dialysis session. At the time of consent and at the end of your mid-week hemodialysis sessions during the study, you will be asked to complete the Dialysis Symptom Index questionnaire. This questionnaire asks about the presence and severity of 30 symptoms that are common in people that receive hemodialysis.

There will be no changes made to your dialysis treatment unless deemed necessary by your nurse or nephrologist as required by your clinical condition.

If you are feeling unwell and/or choose to not cycle on any day over the 4 weeks, we will still measure and record your blood pressure every 15 minutes to compare your non-exercise sessions with your exercise sessions.

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Risks and Discomforts

There is a small risk (<10%) that cycling in the second half hemodialysis may cause more low blood pressure episodes than cycling in the first half of hemodialysis. Otherwise, are no additional risks to participating in this research beyond your routine dialysis treatment and intradialytic cycling program. The researcher may decide to take you out of this study without your consent if your health status changes to prevent you from being able to continue to participate. Your participation in the study may also be discontinued upon the advice of a medical doctor. There is the risk of unintentional release of personal health information.

Benefits

There may or may not be direct benefit to you from participating in this study. We intend to use the information learned from this study to benefit other hemodialysis patients and gain more information about the effects of cycling during hemodialysis.

Costs

All procedures, which will be performed as part of this study, are provided at no cost to you.

Payment for participation

You will receive no payment or reimbursement for any expenses related to taking part in this study.

Alternatives

You do not have to participate in this study to receive treatment for your condition. Please talk to your doctor about all your treatment options.

Confidentiality

Information gathered in this research study may be published or presented in public forums; however your name and other identifying information will not be used or revealed. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba.

Organizations that may inspect and/or copy your research for quality assurance and data analysis include groups such as: The University of Manitoba Biomedical Research Ethics Board.

All study related documents will bear only your assigned study number. All data entered into a computer will be password protected and stored electronically on a research server accessible to members of the research team only. All hard copy records will be kept in a secure locked filing cabinet and only those persons identified will have access to these records.

No information revealing any personal information such as your name, address or telephone number will leave the Health Sciences Centre or Seven Oaks General Hospital. If deemed necessary by the research staff, information regarding your health status may be shared with medical staff at the Health Sciences Centre and/or Seven Oaks General Hospital.

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Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. However, if you decide to stop participating in the study, we encourage you to discuss this decision with the research study staff first. There are no consequences to withdrawing from the study. Your decision not to participate or to withdraw from the study will not affect your care at this centre. If the study staff feels that it is in your best interest to withdraw you from the study, they will remove you without your consent. We will tell you about any new information that may affect your health, welfare, or willingness to remain in this study.

Medical Care for Injury Related to the Study

In the case of injury or illness resulting from this study, necessary medical treatment will be available at no additional cost to you.

Additional Information

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available at http://ClinicalTrials.gov. This website will not include information that can identify you. You can serach this website at any time.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact Monica Sharma at (204) 787-3583 or msharma@exchange.hsc.mb.ca or Dr. Clara Bohm at (204) 787-3583 or CBOHM@exchange.hsc.mb.ca.

For questions about your rights as a research participant, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this information/consent form. I have had the opportunity to discuss this research study with Dr. Clara Bohm and/or her staff. I have had my questions answered by them in a language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor, or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any

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of my records that relate to this study by The University of Manitoba Research Ethics Board for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

I agree to be contacted for future follow-up in relation to this study – YES____ NO____

I would like to receive a summary of the study findings - YES____ NO____

If YES, please provide mailing or e-mail address:
_____

Participant signature: _____ Date: _____
(day/month/year)

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent.

Printed Name: _____ Date:_____
(day/month/year)

Signature: _____ Role in the study: _____

ALL SIGNATORIES MUST DATE THEIR OWN SIGNATURE.

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