Aspireirb
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STUDY APPROVAL NOTIFICATION

The effect of intradialytic resistance exercises using resistance bands with exercise physiologist consultations on the physical function of people undergoing hemodialysis: a proof of concept study

Sponsor:	**Satellite Healthcare**
Protocol Number:	**SH066IDEX** **November 19, 2018 (inclusive of Amendment No. 1)**

The new study listed above was reviewed and approved through expedited review on **December 5, 2018** by **Susan M. Abramson, MD, CIP**, Aspire IRB Board Member.

This study was approved at that time with the following conditions:

- **Informed Consent revised for readability and clarity purposes and to ensure all applicable required elements of consent are satisfied.**

The above-referenced conditions have been met and this study received unconditional approval on December 10, 2018.

Charles Diskin, MD was approved to conduct this study at the following locations:

Satellite Healthcare, Inc.
300 Santana Row, Suite 300
San Jose, CA 95128

Satellite Healthcare Milpitas
1860 Milmont Drive
Milpitas, CA 95035

You must use the enclosed approved consent documentation stamped with "Aspire IRB Approved" located at the bottom of each page.

- **Informed Consent Document dated December 5, 2018**

The IRB has determined that your study is **Minimal** risk. It has been assigned an approval period of **Annual** review. Your approval period ends **December 04, 2019**; as a reminder, you will receive a Research Status Report Form approximately sixty days prior to this date.

The Principal Investigator is responsible for providing the IRB with the necessary materials for re-approval by the due date provided on the form. **This form must be received by the due date to allow ample time for adequate review prior to the study's expiration date.** Missed submissions are the

responsibility of the Principal Investigator regardless of whether or not the IRB notifies you.
The continuation of research after expiration of IRB approval is a violation of the regulations governing research.

Please be aware that while your study has now received IRB approval, FDA approval to proceed is still required (if applicable). It is your responsibility to ensure that you have a valid FDA approval/clearance, before you move forward with study procedures or subject recruitment. It is your responsibility to notify Aspire, if the FDA or any other regulatory agency delays or puts a hold on your research.

It is required that *Aspire IRB* be notified of:

- All amendments or changes to the protocol
- Changes to the protocol that are implemented without prior IRB approval to eliminate an apparent immediate hazard to subjects (must be reported within 24 hours of implementation)
- Unanticipated problems involving risks to subjects or others (within 10 calendar days of discovery) this includes protocol deviations that fit the criteria for an unanticipated problem.
- All material used to recruit study subjects (prior IRB approval is required before use)
- Any other changes in the research activity

The Principal Investigator may not make any changes in the research, without prior approval of *Aspire IRB,* except when necessary to eliminate immediate risk to study subjects. In addition, it is the responsibility of the Principal Investigator to uphold the following three ethical principles outlined in the Belmont Report during the conduct of this study:

- Respect for persons: individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
- Beneficence: maximize possible benefits and minimize possible harms.
- Justice: benefits and burdens of research should be distributed equally.

Aspire IRB is duly constituted and has written procedures in compliance with requirements defined in 21 CFR Parts 50 and 56, 312, 812, 45 CFR 46 and ICH Guidelines relating to Good Clinical Practice. Aspire IRB's mission is to ensure that research is conducted ethically according to the principles of the Belmont Report and in compliance with federal regulations, international regulations, ICH Guidelines for Good Clinical Practice, applicable state and local laws, Aspire IRB Standard Operating Procedures, and that the rights and welfare of human subjects are protected.

Sincerely,

Aspire IRB
AFD

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another has the right to:

(a) Be informed of the nature and purpose of the experiment.

(b) Be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be used.

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment, if applicable.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment or if complications should arise.

(g) Be given an opportunity to ask any questions concerning the experiment or other procedures involved.

(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue in the medical experiment without prejudice.

(i) Be given a copy of a signed and dated written informed consent form when one is required.

(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signature of adult subject capable of consent.	Date

RESEARCH SUBJECT CONSENT FORM

Title: The effect of intradialytic resistance exercises using resistance bands with exercise physiologist consultations on the physical function of people undergoing hemodialysis: a proof of concept study

Protocol No.: SH066IDEX

Sponsor: Satellite Healthcare

Investigator: Dr. C. Dyer Diskin
300 Santana Row, Suite 300
San Jose, CA, 95128
USA

Satellite Milpitas
1860 Milmont Dr, Milpitas, CA 95035

Daytime Phone Number: 605-404-3667
24-hour Phone Number: 605-404-3667

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant. Please take your time to read over this informed consent document to decide if you would like to participate in this research study.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- There will be no change in your physician or dialysis care.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to measure the effect of an exercise program, supported by an exercise professional, for people receiving hemodialysis, compared to people who are receiving hemodialysis who do not take part in the exercise program.
50 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last three months.

What happens to me if I agree to take part in this research?
All patients who agree to take part in this research will be asked to take a few quick physical function tests at the start of the study and at the end of 12 weeks. These measures will consist of sitting and standing from a chair for 30 seconds, walking 8 feet while being timed, and testing your grip strength. At the start of the study, you will also be asked some questions about your energy level and physical activities. These function tests and questions will occur before the start of your dialysis session and should take less than 5 minutes.

You will then be placed randomly (like flipping a coin) either into the control group (no exercise program) of the study or the exercise group. You have a 1 out of 2 chance (50% chance) of being placed in the intervention group which receives the exercise program. You cannot choose your study group. Your study doctor cannot choose whether you are in the exercise group or the control group.

For the patients who are randomized to the exercise group of the study, they will be visited by an exercise professional weekly over a period of 12 weeks. These meetings will occur during your three times weekly in-center hemodialysis sessions. During the initial visits the exercise professional will develop an individualized exercise for you. At subsequent visits they will ask you about how the exercises are going and may alter your regimen based on your answers.

At the end of the study the exercise program you can continue to exercise however this will not be formally supported by the study or the center. All participants will be provided with a summary of the study results at the end of the study.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to:

- Perform 3 physical function tests (1 minute each) at the start and at the end of the study.
- Answer a short questionnaire about your level of energy and physical activity at the start of the trial.
- If you are placed in the exercise group, you will meet with an exercise professional on the days of your regularly scheduled hemodialysis sessions over a period of 12 weeks. These meetings may be before you go on dialysis or while you are on dialysis.

Could being in this research hurt me?
If you are in the exercise program group, starting an exercise program could result in an injury or side effects. Please inform the study doctor or exercise professional if you have any muscle aches, stiffness or joint pains. These symptoms may vary from mild to severe depending on how much exercise your body is used to.

Another possible risk of this study is the disclosure of your private information. All efforts will be made to de-identify your data (surveys and physical function scores) as soon as possible to decrease this risk.

If you are a female, you cannot participate in this research study if you are pregnant.
There may be risks to taking part in this research that are currently unknown.

Will it cost me money to take part in this research?
There will no costs of being in this study and you will not receive payment for participating in the study.

Will being in this research benefit me?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include improved physical function (strength and/or movement) if you are randomized into the intervention group. Possible benefits to others include the success of this study resulting in increased exercise programs for people receiving hemodialysis.

What other choices do I have besides taking part in this research?
This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?
Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research Sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration and the Department of Health and Human Services
- Aspire Independent Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
Data collected in this research will be de-identified and may be used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.
This research is being overseen by Aspire Independent Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-877-366-5414 (toll-free), email@aspire-irb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.

- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?
If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?
The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant
- The research is canceled by the FDA or the sponsor
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?
If you decide to leave this research, contact the research team so that the investigator can describe the procedures for orderly termination by the subject.

Statement of Consent:
I have read and understand the information in this consent form. I have had an opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily agree to participate in this study, until I decide otherwise. I do not give up any of my legal rights as a research subject by signing this consent form. I will receive a copy of this signed consent form.

Your signature documents your consent to take part in this research.

Printed name of adult subject capable of consent	
Signature of adult subject capable of consent	Date
Printed name of person obtaining consent	
Signature of person obtaining consent	Date