Clinical Protocol Statistical Analysis Plan (SAP)

Study Title:	The WISE Trial – Walking Improvement for SCI Exoskeleton
Protocol Number:	105333
NCT:	NCT02943915
Sponsor:	Ekso Bionics, Inc. 1414 Harbour Way S Ste 1201 Richmond, CA 94804
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PARTICIPANT CONSENT FORM FOR RESEARCH – Randomized Group

The WISE Trial: Walking Improvement for SCI with Exoskeleton

Introduction

You are being asked to take part in a research study because you have a spinal cord injury that has impaired your ability to walk and your injury took place at least one year ago. There are many forms of physical therapy and medical devices that could be used to help with your mobility. Ekso Bionics and its representatives ("Sponsor") are sponsoring this study. Ekso Bionics makes one of the devices that will be used in this study.

If you are eligible for this study and agree to participate, you may be asked to use a treadmill or robotic device that helps you to practice walking and to be tested after using the device. Alternatively, you may be asked to not use any other device than you normally do and to participate in the testing only. All of these activities will take place in an Outpatient Rehabilitation Setting. You will be expected to have a series of physical tests and complete a set of questionnaires four to five times during this study. You will be expected to participate in the study for up to 27 weeks.

Your participation in this study is entirely voluntary. This document has important information about the reason for the study, what you will do if you choose to be in this research study and the way the Sponsor and the doctors involved in your care would like to use information about you and your health. You should read the information below and ask questions regarding anything you do not understand prior to deciding whether or not to participate in this study.

If you sign this form, you are giving your permission (or consent) to be a part of this study. You can agree to take part in this study and change your mind later. You should not sign this form if you have any questions that have not been answered.

What is the reason for doing this study?

There will be up to 15 rehabilitation centers participating in this research study. All centers are located in the United States. We are looking for up to 127 people with spinal cord injury to participate in this study. This study is designed to compare 3 different activities that may be used during rehabilitation therapy following spinal cord injury. Participants will be divided into 3 groups. Group 1 will use a device that consists of a brace (exoskeleton) that extends from the trunk (torso) to the feet. It has battery-powered motorized hinges that produce joint motion at the hips and knees, and is capable of producing powered brace-walking. Group 2 will use a bodyweight-supported treadmill device and have other exercises, and Group 3 will continue only with the activities of daily living. All three groups will be evaluated using the same tests.

The primary purpose of this study is to:

1) Determine if using any device (exoskeleton or treadmill) can lead to improvement in walking speed and by how much.
2) Measure the effect of device use on physical performance and stability, quality of walking, and other factors associated with pain, depression and quality of life.

What you will do if you choose to be in this study?
You will be asked to:

- Sign this consent form
- Give your health history
- Undergo a screening evaluation
- Tell the study staff if you take any over-the-counter or prescription medications.
- Females: Tell the study staff if you are currently pregnant or intend to become pregnant in the next 6 months.

If you meet the requirements for study participation, you will be randomly assigned to one of three groups. Randomization is similar to the toss of a coin. Randomization is important when comparing different devices or therapeutic techniques. Your doctor will not know in advance to which group you will be assigned. A description of each group is below:

Group 1: If you are assigned to group 1, you will undergo baseline evaluations and then receive therapy using the exoskeleton device. You will be required to attend therapy 3 times per week for 12 weeks (36 sessions total). Therapy will be provided under the supervision of a Physical Therapist. Each session will last for 60 minutes. Approximately 3 months after your therapy ends, you will be asked to return for final evaluations.

Group 2: If you are assigned to group 2, you will undergo baseline evaluations and then receive standard physical therapy including walking on a treadmill. A Physical Therapist will provide this therapy. You will be required to attend therapy 3 times per week for 12 weeks (36 sessions total). Each session will last for 60 minutes. Approximately 3 months after your therapy ends, you will be asked to return for final evaluations.

Group 3: If you are assigned to group 3, you will undergo baseline evaluations and then continue with daily activities as normal for 12 weeks. No new therapy or medications will be allowed during the first 12 weeks. You will come to the clinic for evaluations as described below. After 12 weeks, you will have the opportunity to choose to have either the exoskeleton (device) therapy, or standard therapy for an additional 12 weeks. The same tests will be done during that time to see if your walking improves.

The study consists of:

- Screening and pre-evaluation period lasting 1-2 weeks (All groups)
- 12 week training period (Groups 1 and 2)
- Evaluations after 6 weeks and 12 weeks of participation. (All groups)
- Group 3 will start therapy after the 12 week evaluation

- Final evaluation at Week 24, or 3 months following the last training session. (Groups 1 and 2):

What are some of the risks and discomforts that may happen? Your participation in this study may involve the following risks:

1) The risk of falling: This could happen if you or your therapist loses control of the walking activity. It may also happen if there is a malfunction of any device that is being used to assist you while walking. Having experienced therapists conduct the training sessions will minimize the risk of falling.

2) Risk of exceeding range of motion: This would be caused if any device moves you beyond your normal range of motion, resulting in a strain, sprain or fracture. For the Ekso device, this risk is lessened by mechanical hard stops that prevent the device from exceeding a normal human range of motion even in the event of an electrical or software failure. Software systems are also in place to further reduce range of motion to improve fit and comfort during walking. You will be evaluated by clinicians who will eliminate you from participation if you cannot meet the required range of motion. For all other devices, this risk will be mitigated through proper settings by the physical therapist in charge of your treatment.

3) Discomfort, skin pressure/friction, bruising, pain, or unusual swelling caused by any device that contacts the skin. This risk will be minimized by a thorough skin check performed by experienced personnel at each training session. Adjustments to the harness placement and additional padding will be assessed to decrease the risk of skin breakdown as well.

4) Blood pressure instability related to standing or activity. This risk will be reduced by frequently checking blood pressure and heart rate prior to training, and as necessary during training and after.

5) Reflex bowel or bladder activity or autonomic instability during walking. This risk will be minimized by requiring you to relieve bowels and bladder prior to walking.

6) Spasms triggered by joint movement in the device. This risk will be reduced through screening prior to enrollment in the study. You cannot take part if your muscles are too stiff.

7) Any device used during this study could malfunction. In the event of device malfunction, you will be able to safely transfer out of the device.

8) There is a risk of fractures when participating in a therapy program: this will be minimized by requiring medical clearance if you are at risk for severe osteoporosis.

9) Risk from loss of confidentiality. To minimize this risk, you will be assigned a unique numeric identifier to be included on test records and test documentation. Research information shared with people outside the study center will not include your name, address, telephone number or any other direct personal identifier unless disclosure of the personal

identifier is required by law. Records may be viewed by the study sponsor and Investigators, study monitors and auditors (such as the Institutional Review Board) who make sure that the study is being done properly.

There may be some risks that are not known.

What are some of the benefits that are likely to come from your being in this study?
Possible benefits may include improved health and independence. However, there may be no direct benefit to you by your participation in this research study and the Sponsor cannot guarantee a benefit to participation..

Are there any financial costs to being in this study?
Ekso Bionics will be responsible for the cost of physical therapy and assessments (evaluations) associated with this research study.

Will I get paid for being in this study?
You will be reimbursed for reasonable transportation expenses (to be judged by the site) related to your participation in this study. If you withdraw from the study early, you will be reimbursed for these expenses for the portion of the study that you did complete.

What happens if I am injured because I took part in this study?
Every effort has been made to ensure that there will be no injuries to you during the study. If you follow the directions of the study doctor and staff and you are physically injured, because of properly given procedures for this study, your insurance may be billed for your care, and if you are not insured, Ekso Bionics, Inc. General and Product Liability Insurance Policy, may cover your medical expenses.

Who can you call if you have questions or concerns about this research study?
You can ask the person discussing this consent form with you if you have any questions If you go home and have questions, or you are injured during your time on this study, you should contact the following person promptly.

Name-
Phone Number -

If you have concerns about your rights, or to offer input you can contact the Institutional Review Board (IRB) XXXXXXXXXXXXXXXXXX

Will my medical information be kept private?
The study doctor and staff will handle your personal health information in a confidential manner. Your health information will be used and disclosed in accordance with the following U.S Data Privacy Statement.

U.S. Data Privacy Statement

A federal government rule has been issued to protect the privacy rights of subjects/patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.
This Data Privacy Statement explains how your personal health information will be used and whom it will be given to ("disclosed") for this research study. It also describes your privacy rights, including your right to see your personal health information.

By signing the consent document for this study, you will give permission ("authorization") for the uses and disclosures of your personal health information that are described in this Data Privacy Statement. If you do not want to allow these uses, you should not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor and staff will use your medical records and information created or collected during the study to conduct the study.
- The study doctor and staff will send your study-related health information ("study data") to the sponsor of the study and its representatives ("sponsor").
- The study data sent by the study doctor to the sponsor does not include your name, address, social security number, or other information that *directly* identifies you. Instead, the study doctor assigns a code number to the study data and may use your initials. Some study data sent to the sponsor may contain information that could be used (perhaps in combination with other information) to identify you (e.g., date of birth). If you have questions about the specific health information that will be sent to the sponsor, you should ask the study doctor.
- The sponsor will use the study data for research purposes to support the scientific objectives of the study described in the consent document, to assess the safety or efficacy of any device or treatment included in the study, to better understand the study indications, or to improve the design of future studies.
- Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries, doctors at other institutions participating in the study, and the ethical review board overseeing this study.
- Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions.

- Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor, the ethical review board overseeing this study, and regulatory authorities in the United States. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law.
- The sponsor works with business partners in device development. The sponsor may share your study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners signs a contract that requires it to protect your study data in the same way as the sponsor.
- The sponsor will not disclose personal health information to insurance companies unless required to do so by law, or due to injury or illness during the study unless you provide separate written consent to do so.

Your medical records and study data may be held and processed on computers.

- You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor or research institution. However, to ensure the scientific integrity of the study, you may not be able to review some of the study information until after the study has been completed.

What are my rights as a research subject?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefits to which you are entitled. Specifically, your choice not to be in this study will have no negative affect on your right to any present or future medical treatment or present or future employment to which you are otherwise entitled.

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.

Please note that:

- You do not have to sign or verbally accept this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.
- You may change your mind and "take back" (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed

for the purpose of this study. To revoke your consent for the use of your health information, you may do so verbally or in writing by notifying the study doctor.

- Unless you revoke your consent, it will not expire.
- Your participation in this study is voluntary and you are free to withdraw at any time. Any new findings developed during the course of this research that may affect your willingness to continue will be provided to you.
- If you choose not to take part in this study, other treatments may be available. Consult with your health care professional to more fully discuss the alternatives.

MANDATORY REPORTING REGARDING ELDER/DISABLED

Ekso Bionics is a mandatory reporter under the Elder Abuse and Dependent Adult Civil Protection Act. Under California law, Ekso Bionics will not maintain as confidential, information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect. If any Ekso Bionics employee has or is given such information, he or she may be required to report it to the authorities.

Optional Elements [Choose One]:

_____(Initial) I give permission for photographs or videotapes of me that DO include my face to be used in scientific publications, presentations, marketing or publicity materials.

_____(Initial) I give permission for photographs or videotapes of me that DO NOT include my face to be used in scientific publications, presentations, marketing or publicity materials.

_____(Initial) I DO NOT give permission for photographs or videotapes of me to be used in scientific publications, presentations, marketing or publicity materials.

Consent Summary:
I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above.

A copy of this consent form will be provided to me after I sign it.

_____

Subject's Name (printed) (signature) Date

_____

Name of Person Obtaining Consent (printed) (signature) Date

Subject unable to sign due to _____ . Subject gave verbal permission.

_____

Witness Name (printed) (signature) Date

[Can be the person obtaining the signature of the subject or of the subject's personal representative]

_____

Principal Investigator (printed) (signature)