IRB APPROVED
AS MODIFIED
Jun 05, 2024

RESEARCH SUBJECT CONSENT FORM

TITLE:	Clinical Evaluation of Perineal Electrical Stimulation for Urinary Incontinence in Men
PROTOCOL NO.:	TR-1168 WCG IRB Protocol #20240538
SPONSOR:	Elidah, Inc.
INVESTIGATOR:	Gloria Kolb, MBA, BS, MS 810 Main Street, Ste C Monroe, CT 06468 United States
STUDY-RELATED PHONE NUMBER(S):	978-435-4324 781-985-0563 (24 hours)

Informational

Do not sign

this copy

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This portion provides a concise summary of this research. Later sections of this document will provide all relevant details.

Overview

The purpose of this research is to evaluate the effectiveness of the Elidah neuromuscular stimulation treatment to reduce incontinence in men post-prostatectomy. There are two arms: Arm A is within 4 weeks of prostatectomy, Arm B is longer than 4 weeks after prostatectomy.

We expect that your taking part in this research will last 7 (13 for Arm A) weeks and consist of:

- Self-administer electrical stimulation using the Elidah device, 20 minutes per session, 5x per week for 6 weeks.
- Keep a daily record of pad usage, urine leaks, bathroom visits and device usage for 7 weeks (1 week baseline + 6 weeks during treatment).
- Record the weight of pads used during a 24-hr period, 3x each during baseline week, 6th week and for Arm A again at the Follow-up at 12 weeks.
- Answer questionnaires on history, quality of life, incontinence, and other matters pre- and post treatment, and a short version at the follow-up time periods.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include:

- Skin irritation such as redness, itching or sensitivity from the GelPad. This typically disappears after treatment has stopped.
- Pain or discomfort from pulling of the skin/hair. Applying the GelPad in the correct position and confirming that it is secure and in direct skin contact will help alleviate the pulling and minimize the discomfort.
- Electrical shock; this is minimized by not using the device while charging and intensity of the shock being controlled by the user.
- Pelvic muscle fatigue, which may increase urine leakage. If this occurs, it typically resolves after treatment has stopped.

Risks can be minimized by following the Instructions for Use (i.e. User Manual). If you experience any discomfort of side effects, you must tell the investigator or study staff. If you do not share this information with the staff, it may be unsafe for you to continue in the study.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will being in this research benefit me?

The most important possible benefits that you may expect from taking part in this research include:

- Reduction of incontinence symptoms and episodes
- Faster reduction of incontinence than on your own
- Improved quality of life
- Reduction in cost of the symptoms- such as reduction of pads, diapers, laundry, etc.
- Better understanding of urinary incontinence that may lead to new and improved treatments.

Possible benefits to others include an over-the-counter, accessible treatment to help men with incontinence in the future.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include pelvic floor physical therapy, Kegel exercises, and neuromuscular stimulation with an anal probe or with a magnetic chair in a clinical office.

What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is a similar device has been regulatory approved and used by women.

DETAILED RESEARCH CONSENT

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.

Why is this research being done?

The purpose of this research is to evaluate the effectiveness of the Elidah neuromuscular stimulation treatment to reduce incontinence in men post-prostatectomy.

About 30 subjects will take part in this research.

How long will I be in this research?

We expect that your participation in this research will last 13 weeks. Most of the activities are during the first 7 weeks, and then there are follow-up activities on the last week.

What happens to me if I agree to take part in this research?

As a part of this research, you will wear the study device 5x a week for six weeks at your home (about 30 times in total). The device is worn on the perineal area for 20 minutes for each experimental treatment. You may get dressed and do other activities while the device is in use.

The Elitone device is FDA-cleared to treat incontinence for women. The Elidah device is investigational for men, which means that it is not approved by the Food and Drug Administration (FDA) for men.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to (at-home or online):

- Read all instructions prior to use, including the User Manual.
- Use only as directed.
- If you are currently taking medication, you should not change the medication during this study.
- Self-administer electrical stimulation using the Elidah device, 20 minutes per session, 5x per week for 6 weeks.
- Keep a daily record of pad usage, urine leaks, bathroom visits and device usage for 7 weeks (1 week baseline + 6 weeks during treatment).
- Record the weight of pads used during a 24-hr period, 3x each during baseline week, 6th week and for Arm A again at the Follow-up at 12 weeks.
- Answer questionnaires on history, quality of life, incontinence, and other matters pre- and post treatment, and a short version at the follow-up time periods.
- Return study materials in a timely manner in prepaid mailer.

Schedule of Subject Activities/Requirements.

	Pre-Study Q	I-QoL Q	SHIM Q	3x Pad Weights	Number of Treatments	Daily Log	Post-Study Q	Follow-up Q (Arm A)
Screening /History /Consent /Training								
Prostatectomy /Confirm incontinence /Send materials								
Pre-Treatment Baseline (Week 0)	●	●	●	●		●		
Treat (Week 1)					5	●		
Treat (Week 2)					5	●		
Treat (Week 3)					5	●		
Treat (Week 4)					5	●		
Treat (Week 5)					5	●		
Treat (Week 6)		●	●	●	5	●	●	
Weeks 7-11					optional			
Follow-up Data (Week 12 for Arm A)				●		●		●

Read the precautions below:

- The long-term effects of chronic muscle stimulation are unknown.
- The device is intended for indoor use only.
- Exposure of the Controller to liquids may result in personal injury or damage to the device. Do not use while bathing, swimming, or otherwise submerged.
- Discontinue treatment and consult a healthcare provider if you feel light-headed or faint while using the device.
- Use of equipment should be discontinued upon signs of treatment-related stress or discomfort.
- The device should not be used while driving, operating machinery, or any other activity in which involuntary muscle contraction may put the user at risk.
- Only apply the GelPad to normal, intact, clean, healthy skin.
- Do not place the GelPad over or in proximity to cancerous lesions, open wounds, rashes, recent scars, swollen, red infected or inflamed tissue, or skin that is susceptible to acne, thrombosis or other vascular problems.
- Use caution if GelPad application area lacks normal sensation.
- Keep device out of reach of children and pets. Elidah device is for use by adults only.
- Do not attempt to use the device while it is charging or connected to the charging cable.
- Do not use the product while sleeping.
- Best results may be achieved by removing/trimming hair from the application site.
- Do not use the device with any other product which delivers electrical current to the body (e.g. muscle stimulators, high frequency surgical equipment) as this could result in burns or other injury.

- Do not apply stimulation in the presence of electronic monitoring equipment (e.g. cardiac monitors, ECG alarms), which may not operate properly when the device is in use.
- Do not use in close proximity (e.g. 1 meter) to shortwave or microwave therapy equipment, as this may produce instability in the Controller's output.
- Wireless communication equipment such as wireless home network devices, mobile phones, cordless telephones, base stations, and walkie-talkies can affect this device.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include:

- Skin irritation such as redness, itching or sensitivity from the GelPad. This typically disappears after treatment has stopped.
- Pain or discomfort from pulling of the skin/hair. Applying the GelPad in the correct position and confirming that it is secure and in direct skin contact will help alleviate the pulling and minimize the discomfort.
- Electrical shock; this is minimized by not using the device while charging and intensity of the shock being controlled by the user.
- Pelvic muscle fatigue, which may increase urine leakage. If this occurs, it typically resolves after treatment has stopped.

Risks can be minimized by following the Instructions for Use (i.e. User Manual). If you experience any discomfort of side effects, you must tell the investigator or study staff. If you do not share this information with the staff, it may be unsafe for you to continue in the study.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost me money to take part in this research?

Taking part in this research may lead to added costs to you, such as: cost of absorbent pads.

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:

- Reduction of incontinence symptoms and episodes
- Faster reduction of incontinence than on your own
- Improved quality of life
- Reduction in cost of the symptoms- such as reduction of pads, diapers, laundry, etc.
- Better understanding of urinary incontinence that may lead to new and improved treatments.

Possible benefits to others include an over-the-counter, accessible treatment to help men with incontinence in the future.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include pelvic floor physical therapy, Kegel

exercises, and neuromuscular stimulation with an anal probe or with a magnetic chair in a clinical office.

What happens to the information collected for this research?

Your private information, your study record, 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
- WCG IRB, the Institutional 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.

Does the Investigator have a financial interest in this research?

The principal investigator owns the sponsor company. Please feel free to ask any question you may have.

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(s) listed in this document.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may contact them at 855-818-2289 or clientcare@wcgclinical.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 Investigator immediately. See your doctor for emergency medical treatment, who should treat you or refer you for 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, and that all directions from the study and device were followed. 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 do not adhere to the study protocol

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. You may be asked by the investigator to:

- Fill out final questionnaires
- Return the components given to you at the beginning of the study

If you decide to leave the research early, any information that you gave before your withdrawal may be used.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $100 (up to $250 for Arm A) in Visa-type gift cards for completion of the study at the end of the entire study and upon confirmation of completeness. Additionally, you may keep the study device (after we check it after the 6 weeks of treatment) if you choose.

Statement of Consent:

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

Signature of subject	Date
Signature of person obtaining consent	Date