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Study Title: Efficacy of Low-Intensity Extracorporeal Shockwave Therapy in Treatment of Erectile Dysfunction – A Randomized Controlled Trial with Sham Therapy

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Patient Information Sheet

Efficacy of Low-Intensity Extracorporeal Shockwave Therapy in Treatment of Erectile Dysfunction – A randomized controlled trial with sham therapy

Principal Investigator: Dr Kwun-Chung CHENG, Division of Urology, Department of Surgery, United Christian Hospital.

You are cordially invited to participate in the above research study. Approximately 84 erectile dysfunction patients in total will be invited to join this study in Division of Urology, Department of Surgery at United Christian Hospital and Tseung Kwan O Hospital. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your family doctor if you wish. Please take time to decide whether or not you wish to take part. You are encouraged to discuss with your partner before taking part in this study. If you would like more information or have any questions regarding the research, please feel free to contact us.

Introduction

Hong Kong has an aging population. By the year of 2036, more than 30% of our population will be older than 65 years old1. Aging in male has been shown to correlate with the risk of erectile dysfunction(ED). The demand in ED treatment is expected to increase.

Several ED treatment options are currently available, but none of these treatment are curative nor rectify the pathophysiology of ED. A common cause of ED in men was vascular insufficiency due to atherosclerosis. Shockwave could induce new blood vessels formation in penis, thus rectify the underlying vascular insufficiency. Low-intensity extra-corporeal shockwave therapy (LI-ESWT) has been introduced since 2010 for treatment of ED. Efficacy has been proven by early studies, including a local study conducted by the Chinese University of Hong Kong in 2015. Nonetheless, the available studies were criticized for the variations in shockwave generators, energy parameters and treatment protocol. Most studies used focused electrohydraulic machines, did not include nocturnal penile tumescence (NPT) as part of the outcomes assessment, and only reported the short-term outcomes. (NPT is a test conducted with a small handheld machine. The machine would record your night time erection hardness.)

Purpose of the research

The aim of this study is to investigate the efficacy and safety of LI-ESWT in treatment of moderate and severe ED, and to evaluate the effect of LI-ESWT on nocturnal penile tumescence and rigidity.

Procedure

After informed consent was obtained, your background and disease-related information will be collected. You will be randomly allocated to one of the following two treatment options (50% chance for each arm) with a random number table:

1. Low-intensity Extracorporeal Shockwave Therapy

2. Sham therapy

You would undergo a 4-week washout period of oral phosphodiesterase inhibitors after recruitment. Severity of ED would be assessed by the International Index of Erectile Function – Erectile Function Domain (IIEF-EF) & International Index of Erectile Function (IIEF-5) questionnaires and EHS after the washout. Nocturnal penile tumescence (NPT) and rigidity would be measured by the Rigiscan at the night prior to the first treatment. A handheld Rigiscan machine would be given to you for home measurement. Instruction would be given on the use of the machine. Two measurement ring would be put over the penis for overnight measurement on the change of length and girth. You should return the machine to investigator on next day.

All procedures would be performed by a designated nurse consultant (Study Investigator: Mr. Jan Ching) in an office setting using an electromagnetic linear shockwave machine.

Treatment consists of 6 sessions over 5 weeks in total. It would be a twice-weekly treatment with one-week interval of resting period. Patient would be discharged home after each treatment session.

You would have to attend three consultations for clinical assessment at week 4, week 26 and week 52 after completion of treatment. NPT would be measured at week 4 and week 52. At all follow-up the IIEF-EF questionnaires and EHS would be assessed. Each assessment would take approximately 15minutes. All clinical consultation, assessment and treatment would be conducted in Tseung Kwan O Hospital.

Alternative Procedures or Treatments

If you have decided not to join this study, you could still choose other usual standard treatment for erectile dysfunction(e.g. oral drugs, injection therapy etc.). Your study doctor will talk to you about other possible treatments, their risks and benefits.

Potential risks/ discomforts and complications

There were no severe complications reported after treatment in the literature. In some cases penile discomfort and urethral bleeding had been reported. Any complications would be assessed and documented according to Clavien-Dindo classification.

Potential Benefits

You will not receive any direct benefits from participation in this study, but it will help in gaining better insight into management of the disease; which will eventually result in improved patient care.

Cost and Payment of the Study

Except regular medical care fees, you do not need to pay for the device; nor will you receive any payment upon participating into the study.

Expected Duration of Research

The study will last for approximately 44 months.

New Information

You will be updated timely of new information that may be relevant to your willingness to continue participation in study.

Voluntary participation/ Withdrawal / Termination

Participation in the study is voluntary. Your decision to participate or not will be respected. You have the right to terminate your participation at any time and without giving any reason during the study, and this will not affect your present or future medical care. If you feel uncomfortable in any way during the session, you may not continue to participate in the study. If you withdraw from the study, the data collected up to your withdrawal will not be used unless with your consent. You may also express your consent to research team through Informed Consent Form to allow research team to continuously use data collected before your withdrawal for research purpose. You can take time to decide whether or not you wish to take part. By signing an informed consent form, you will be given a patient information sheet and a signed copy of the informed consent form for record.

Compensation and treatment for study related injury

If your participation in this study caused any physical injury or feel uncomfortable emotionally, the investigator will treat you or refer you for treatment. You are not giving up any of your legal rights by signing this form.

Confidentiality

Your confidentiality will be the highest priority. If the information you provide is reported or published, this will be done in a way that does not identify you as its source. To ensure the highest form of confidentiality, we do not fill in your name on the information. Your signed informed consent form will be stored separately from your personal data to further protect your confidentiality. Access to the data will be restricted to the researchers of this study. Along with this, the personal data will be stored in the computers which are only accessible by the researchers. Data can be withdrawn and destroyed if requested by you and all data will be destroyed five years after the completion of the study.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By signing a written informed consent form, you are authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) will be granted direct access to your study data for data verification.

Enquiry

If you have any further queries regarding the research study, you may contact the following study investigators:

Dr CHENG Kwun Chung, Associate Consultant, Division of Urology, Department of Surgery, United Christian Hospital at 3949-4000.

Mr. CHING Lok Sang Jan, Nurse Consultant, Nursing Service Division, Kowloon East Cluster at 5215-7224.

If you have questions related to your rights as a research participant, please contact Research Ethics Committee (Kowloon Central/Kowloon East) at 3506-8888.

Informed Consent Form

Efficacy of Low-Intensity Extracorporeal Shockwave Therapy in Treatment of Erectile Dysfunction – A randomized controlled trial with sham therapy

Principal Investigator: Dr Kwun-Chung CHENG, Division of Urology, Department of Surgery, United Christian Hospital.

I hereby consent to participate in the research study.

I have read the PATIENT INFORMATION SHEET. The study team has been explained to me. I understood all the benefits and the risks associated with this study. I have had opportunities to ask questions and all my questions have been satisfactorily answered. I have received enough information about the study.

If the result of my participation in this study caused any physical injury or feel uncomfortable emotionally, the investigator will treat me or refer me for treatment. I am not giving up any of my legal rights by signing this form.

By signing this consent form, I certify that all information provided is true and correct. I understand that I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and the withdrawal will not affect my present and future medical care.

If I request to withdraw from this study, I ☐ agree / ☐ disagree my research data provided before my withdrawal will be continuously used by the investigator.

I understand that my identity will be kept confidential. I agree to authorize the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to my research data for verification of clinical trial data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.

_____	_____	_____
Participant's Name (in BLOCK Letter)	Participant's Signature	Date

_____	_____	_____
Participant's Legally Authorized Representative Name, if applicable (in BLOCK Letter)	Participant's Legally Authorized Representative's Signature	Date

The legally authorized representative's consent should be obtained if the participants are incapable of giving consent.

_____	_____	_____
Impartial Witness's Name, if Applicable (in Block Letter)	Impartial Witness' Signature	Date

An impartial witness's signature should be included if the participant is unable to read or write.

_____	_____	_____
Investigator's Name (in BLOCK Letter)	Investigator's Signature	Date

I will be given a patient information sheet and a signed copy of this informed consent form.