Clinical study on the treatment of pelvic pain with wearable dual-band LED device

Informed consent

2023.1

Informed consent

Protocol name: Clinical study on the treatment ofpelvic pain with wearable dual-band LED device

Setting: the Third Hospital of Peking University

Main researcher: Chief gynecologist Guo Hongyan

Patient name: Initials:

Patient's address: Patient's number:

We cordially invite you to participate in the“Clinical study on the treatment ofpelvic pain with wearable dual-band LED device”. Here are some questions you may be interested in:

[Background]

Dysmenorrhea and chronic pelvic pain are the main causes ofpelvic pain in women. The severe abdominal pain has seriously affected women's normal life and work, significantly reducing their quality of life. dysmenorrhea is divided into Primary and secondary types. Primary dysmenorrhea (PD) refers to periodic spasmodic pelvic pain that occurs when no organic lesions are found in the uterus, ovaries and fallopian tubes. Secondary dysmenorrhea refers to pain related to diseases such as endometriosis, pelvic inflammatory disease, leiomyoma and interstitial cystitis. Chronic pelvic pain refers to pelvic pain that lasts non-periodically for more than six months and is unresponsive to non-opioid drug treatment. It is often caused by organic lesions such as endometriosis, adenomyosis, and pelvic adhesions. For the treatment of dysmenorrhea and chronic pelvic pain, the commonly used treatment methods at present include oral short-acting contraceptives, non-steroidal anti-inflammatory drugs, painkillers, traditional Chinese medicine, acupuncture, physical therapy and surgical treatment, etc. However, whether it is traditional Chinese medicine or Western medicine, acupuncture or surgical treatment all have non-negligible toxic and side effects as well as risks. Therefore, an alternative therapy or combined treatment is needed to mitigate these side effects.

Photobiomodulation (PBMs) refers to the biological responses caused by irradiating corresponding tissues or cells with lasers of specific wavelengths or

light-emitting diodes (leds). It has been applied to various diseases, including rheumatoid arthritis, osteoporosis, wound healing and analgesia. The intrinsic mechanism ofPBMs is to enhance the production of mitochondrial ATP, cellular signal transduction and the synthesis of growth factors, and to weaken oxidative stress. Studies both at home and abroad have shown that 630m red light irradiation through acupoints or wearing a far-infrared light belt on the abdomen during menstruation can effectively relieve dysmenorrhea. For pelvic myofascial pain, the SoLa pelvic treatment device has significantly treated the pelvic pain ofpatients in foreign clinical practice.

In order to better solve the problems of dysmenorrhea and chronic pelvic pain in women and improve the quality of life of women, this study designed and developed wearable dual-band LED devices for the treatment ofpelvic pain. In the future, our LED devices will also be applied in clinical practice, serving the public and enhancing the well-being of women's lives.

[Objective]

The aim of this project is to establish a bidirectional multicenter cohort of LED treating pelvic pain in our country. During the non-menstrual period, dual-band LED devices were worn to perform low-dose phototherapy on the local pelvic area and acupoints, and the changes ofpelvic pain and related serological indicators were observed clinically.

[Study design]

The aim of this project is to establish a bidirectional multicenter cohort of LED treating pelvic pain in our country. During the non-menstrual period, dual-band LED devices were worn to perform low-dose phototherapy on the local pelvic area and acupoints, and the changes ofpelvic pain and related serological indicators were observed clinically.

Inclusion criteria:

1)Age: 18-35 years old;

2) Regular menstrual cycle

3) Those who can voluntarily sign the informed consent form

Exclusion criteria:

1) Irregular menstrual cycle

2) Pelvic inflammatory disease

3) The pregnancy screening test is positive

4) Phototherapy allergy

5) Patients who have suffered from malignant tumors and are currently undergoing treatment

6) Suffering from serious internal or mental diseases or neurological disorders that affect informed consent and/or the expression or observation of adverse reactions

7) Those who have participated in other clinical trials within the past three months.

Withdrawal Criteria:

1) The subject requested to withdraw from the clinical trial;

2) Those who experienced serious adverse events during the trial;

3) Those whose conditions have progressed during the trial and are not suitable to continue with this research protocol;

4) The researcher or/and sponsor consider that the patient does not meet the experimental requirements and is not suitable to continue participating in this study.

Patients with dysmenorrhea

1) After signing this study, the VAS pain scores of each day during the first menstrual period after enrollment were recorded. On the second day of menstruation, the gynecological outpatient department was visited for tests such as urine pregnancy test, blood routine, urine routine, liver and kidney function, and serum markers (CA125, PGE2, PGF2α, leukotriene C4, D4, and nitric oxide levels). Come to the gynecology outpatient department again at the appointed time (the 14th day of menstruation) for gynecological ultrasound (blood flow in the uterine artery and endometrium), distribute the equipment and guide the operation of the equipment.

2) During the 2nd to 4th menstrual cycles after enrollment, the device was used for treatment. Starting one week before each menstrual cycle, it was used once a day for

30 minutes each time. The VAS pain score of each menstrual period was recorded. A total of 3 menstrual cycles were treated.

3) On the second day of the fourth menstrual period after enrollment, go to the gynecology outpatient department for tests of blood routine, urine routine, liver and kidney function, and serum markers (CA125, PGE2, PGF2α, leukotriene C4, D4, nitric oxide level). Come to the gynecology clinic again at the appointed time (the 14th day ofyour period) for a gynecological ultrasound and return the equipment.

4) During the treatment process, prepare painkillers (ibuprofen). If the pelvic pain is unbearable, oral painkillers can be taken. Record the time and dosage of medication.
Patients with chronic pelvic pain

1) After signing this study, the VAS pain scores of each day during the first menstrual cycle after enrollment were recorded. On the second day of menstruation, the patients went to the gynecological outpatient department for tests such as urine pregnancy test, blood routine, urine routine, liver and kidney function, and serum markers (CA125, PGE2, PGF2α, leukotriene C4, D4, nitric oxide level). Come to the gynecology outpatient department again at the appointed time (the 14th day of menstruation) for gynecological ultrasound (blood flow in the uterine artery and endometrium), distribute the equipment and guide the operation of the equipment.

2) During the 2nd to 4th menstrual cycles after enrollment, the device was used for treatment. It was used once a day during the non-menstrual period, for 30 minutes each time. The pain score of the treatment cycle was recorded. A total of 3 menstrual cycles were treated.

3) On the second day of the fourth menstrual period after enrollment, go to the gynecology outpatient department for tests of blood routine, urine routine, liver and kidney function, and serum markers (CA125, PGE2, PGF2α, leukotriene C4, D4, nitric oxide level). Come to the gynecology outpatient department again at the appointed time (the 14th day of menstruation) for gynecological ultrasound (blood flow in the uterine artery and endometrium), and return the equipment.

4) During the treatment process, prepare painkillers (ibuprofen). If the pelvic pain is unbearable, oral painkillers can be taken. Record the time and dosage of medication.

[Study test]

Urine pregnancy test, blood routine, urine routine, liver and kidney function and serum markers, gynecological B-ultrasound

[Study duration and follow-up]

If you participate in this study, you will need to visit the hospital four times, namely on the 1st and 14th days of the first menstrual cycle after enrollment, and on the 1st and 14th days of the fourth menstrual cycle. Each time you visit the hospital, you need to stay there for 1 to 2 hours.

[Risks]

During the treatment ofpelvic pain with wearable dual-band LED devices, there may be brief rashes, itching and weight loss, which are mild and generally do not require special treatment. Very few people may experience local pain. There is a possibility that the treatment may fail and the pain may not be relieved, requiring oral painkillers and other medications.

[If these drugs are used in the study, the study can not be continued]

Short-acting contraceptives, dinogestrel and GnRha are not allowed to be used during the treatment period.

[Expenses and compensation]

This study will exempt you from the cost of genetic testing for family members other than the proband.

[Benefit]

This study can waive the costs of 1. Blood routine, urine routine, liver and kidney function tests, and gynecological ultrasound for you. 2. A travel subsidy of 50 yuan per person per trip to and from the hospital

[Possible reasons for termination]

Your participation in the trial is voluntary. You can refuse to participate or withdraw from the trial at any stage and in any way without discrimination or retaliation. Your medical treatment and rights will not be affected, but all unused research devices should be returned. If you experience severe adverse reactions, or ifyour pelvic pain becomes intolerable or worsens during the treatment process, or ifyou have adverse

reactions such as an allergy to red light, or ifyour research doctor deems that continuing to participate in the study is not in your best interest, he/she will decide to withdraw you from the study. If this happens, we will notify you in a timely manner and your research doctor will also discuss with you the other options you have. If the doctor believes that suddenly interrupting the trial will affect your health, they may ask you to come to the hospital for a check-up before stopping the trial.

[New information]

You will be informed of any new research findings and new treatments that arise in the course ofyour research.

[Privacy and confidentiality]

During the study period, your name, gender and other personal data will be replaced with code names or numbers, and be strictly confidential. Only the relevant doctors know your data and your privacy will be well protected. The results may be published in a journal, but will not reveal any ofyour personal information.

[How to communicate with doctors and researchers during treatment]

If you have any questions related to this study, please contact Dr. Wu Zhangxin at 18610689868; If you need to know about the participants' rights during the study, you can contact the Ethics Committee Office ofPeking University Third Hospital at (010)82265571/82265176.

[Notification Statement]

"I have informed the subject of the background, objectives, steps, risks and benefits of the study (Clinical study on the treatment ofpelvic pain with wearable dual-band LED device) , given him/her sufficient time to read the informed consent, discuss with others, and answer questions about the study; I have informed the subject that he/she can contact (the researcher) at any time when he/she encounters problems related to the study, and that he/she can contact the General Office of Scientific Research Ethics of Peking University Third Hospital whenever he/she encounters problems related to his/her rights/interests, and provided accurate contact details; I have informed the subject that he/she can withdraw from the study at any time

without any reason; I have informed the subject that he/she will be given a copy of the informed consent, which includes my signature and his/her signature."

Signature of the researcher who obtain informed consent

_____

Contact telephone

_____

Date

_____

[Statement of informed consent]

I have been informed of the background, objectives, procedures, risks and benefits of the study. I had enough time and opportunity to ask questions and I was satisfied with the answers. I was also told who to contact when I had questions, grievances, concerns, or wanted further information. I have read this informed consent form, agreed to participate in this study, and promised to provide researchers with information, laboratory test results are true and effective. I know that I can withdraw from this study at any time without any reason. I was told that I would receive a copy of this informed consent form, which included my signature and that of the researcher.

Signature of the subject

_____

Contact telephone

_____

Date

_____