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

Study protocal

2023.1

Program design

[Design of the study methodology]

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.

[Eligibility, exclusion and withdrawal criteria]

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.

[Study duration and follow-up]

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.

Data management

1. Data Entry

Data collection will be obtained by team staff via the Case Report Form (CRF). As a part of the clinical data management system, the case report form for data collection is jointly negotiated and prepared by the project leader and the clinical epidemiology Research Center, and the experts are invited to discuss and modify it for use. The data collation process includes automated validation procedures and manual validation to ensure the completeness and accuracy of the data entered into the case report form. When the data does not match, the data can be queried, and the team staff can verify and modify the entered data.

2. Contents and methods of data verification and management

According to the data entered in the case report form, medical supervision is conducted regularly to ensure the accuracy of data entry, and medical problems are discussed separately.

3. Data Archiving

After data entry and verification are completed as required, the case report form shall be filed and stored in numbered order, and be filled with a retrieval catalogue for reference. Electronic data files, including databases, inspection programs, analysis programs, analysis results, coding and explanatory files, should be classified and stored in different disks or recording media with multiple backups, properly stored to prevent damage. All original files shall be kept for the period specified accordingly.

Statistical analysis

Based on the assessment of traditional Chinese medicine practitioners in prospective clinical trials combined with the treatment intentions of patients, various control groups were formed. Appropriate clinical research methods were selected for statistical analysis.