Efficacy and safety of photodynamic therapy for cervical intraepithelial neoplasia 3(CIN3):A multicenter prospective cohort study

Informed consent

2025.5

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Protocol name: Efficacy and safety of photodynamic therapy for cervical intraepithelial neoplasia 3(CIN 3) :A multicenter prospective cohort study

Setting: 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“Efficacy and safety of photodynamic therapy for cervical intraepithelial neoplasia 3(CIN 3) :A multicenter prospective cohort study” . Here are some questions you may be interested in:

[Background]

Intraepithelial neoplasia of the lower reproductive tract in women, including LSIL and HSIL of the cervix and vagina (including CIN1, CIN2, and CIN3 of the cervix and VaIN1, VaIN2, and VaIN3 of the vagina), the main treatment methods are surgical resection and physical therapy. Conization of the cervix can affect fertility and cause miscarriage and premature birth. The lesions of the vagina and vulva are widely distributed and have special histological structures. Surgical resection is often difficult to completely remove and the difficulty of shaping and reconstruction is high. Traditional physical therapies, such as cryotherapy and CO2 laser vaporization, have an effective rate of approximately 60-90%.

Photodynamic Therapy (PDT) is a new technology that selectively treats the lesion site by using photodynamic reactions. The amount of photosensitizer retained in the tissue cells of the lesion site with active metabolism is higher than that in normal tissue cells. When the lesion site is irradiated with a laser of a certain energy and specific wavelength, the photosensitizer is stimulated to undergo a photodynamic reaction, which directly kills the tumor cells. In developed countries such as the United States, Europe and Japan, photodynamic therapy, as a new technology for treating tumors and precancerous lesions, has long been reviewed and approved by government authorities. Photodynamic therapy has become a routine treatment method for various tumors including esophageal cancer, lung cancer, bladder cancer and breast cancer. Photodynamic therapy has the advantages of good tissue selectivity, strong damage to microvessels, small trauma, low toxicity, good applicability, repeatability and palliative treatment, synergistic surgery to improve

therapeutic effect, eliminate latent cancer foci and protect the structure and function of important organs. For patients with precancerous lesions of the lower reproductive tract, photodynamic therapy retains organ integrity. Especially for young patients with cervical lesions who have fertility requirements, photodynamic therapy can reduce the occurrence of premature birth, miscarriage and other conditions caused by cervical insufficiency. Some scholars speculate that photodynamic therapy may replace surgical treatment in the treatment of precancerous lesions of the lower reproductive tract and become the preferred therapy.

This research has been approved by the ethics committee of this research center.

[Objective]

The aim of this project is to study the efficacy and safety of photodynamic therapy (20% 5-aminolivulonic acid +630nm red light) in the treatment of cervical intraepithelial neoplasia 3(CIN3) in women in real-world applications.

[Study design]

We invite you to participate in this study because you have chosen photodynamic therapy for the treatment of CIN 3 and initially meet the following basic conditions.

Inclusion Criteria:

-CIN3, photodynamic therapy was required,

-type 1 2 transformation area, colposcopy was sufficient

-the lesion boundary was completely visible

-The ECC did not indicate high-grade lesions

Exclusion Criteria:

-coexistence or suspicion of cancer;

-TCT HSIL

-involving glands

-Porphyria patients, or suspected allergic to red and blue light.

-severe medical comorbidities;

Withdrawal Criteria:

- The subject requested to withdraw from the clinical trial;

- Those who experienced serious adverse events during the trial;

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

- 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.

The specific implementation steps are as follows:

After enrollment, the subjects signed the informed consent form and made an appointment for the first treatment time. No treatment was given 3 days before and after menstruation.

For the first treatment, after the patient ate, the bladder was emptied, the lithotomy position of the bladder was taken, the cervix was exposed with a endoscope, the vaginal secretions of the cervix were wiped with a dry gauze ball, 20% aminolevulonic acid photosensitizer (5-ALA) was applied to the lesion site, a cotton condom was stuffed into the vagina, and the patient was instructed to sit still and wait for 3-4 hours. Avoid activities during this period, reduce walking and urination. Four hours later, the patient lay on the examination bed again and was irradiated with red light at 630-635nm. After the treatment is completed, observe for half an hour. If there is no discomfort, you can leave the hospital. Before leaving, an adverse reaction record card will be issued. Make an appointment for treatment 7 days later. If it falls during menstruation, it will be postponed by one week.

For the 2nd and 3rd treatments, the parameters and energy density are the same as those of the first one. The treatment interval is 7 days. If it falls during the menstrual period, it will be postponed by one week.

One month after the end of the third treatment, colposcopy was performed. If the suspected lesion worsened, a biopsy was taken. If no abnormalities are found under colposcopy, a single-point biopsy is taken at the most severe site of the original lesion. If the biopsy indicates that the lesion persists, continue the treatment for three times. TCT+HPV was reexamined 6 months after the start of the first treatment. If the lesion worsens, the patient will be referred for surgical resection in accordance with the diagnosis and treatment norms.

The research data collected during the study included the basic information of the patients, the test and examination results before and during the treatment, the dosage of the treatment medication and phototherapy parameters, the results of the treatment effect evaluation, the adverse reactions of the treatment and the subsequent follow-up. All these information were necessary for the normal diagnosis and treatment process and no additional clinical data of the patients were collected for this study.

[Study test]

Urine pregnancy test, coposcopy.

[Study duration and follow-up]

There is no need to come to the hospital separately.

[Risks]

Any drug treatment may bring discomfort and unpredictable risks to patients. According to relevant clinical research data, the main adverse reactions after treatment with the photodynamic therapy group drugs (local use of aminolevulinic acid hydrochloride powder) were burning sensation, pain, itching, a feeling of lower abdominal distension, increased vaginal discharge, and mild local bleeding of the cervix at the treatment site. These local reactions generally do not require treatment and can recover spontaneously in a short period of time.

Your research doctor will monitor the side effects. If you experience any side effects or discomfort during the study period, it is crucial that you report it to your study doctor immediately. The research doctor will take treatment measures in time. If you or your research doctor believe that you cannot tolerate these side effects, you may consider other treatment options.

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

No.

[Expenses and compensation]

No.

[Benefit]

You may not directly benefit from this study, but the information obtained in this study will be helpful for the selection of treatment plans for cervical and vaginal intraepithelial neoplasia in women and will be of great assistance to the treatment of other patients with the same disease as yours.

[Possible reasons for termination]

You can discuss and decide on the treatment method with your doctor. The subjects enrolled in this study were patients who received photodynamic therapy for cervical and vaginal intraepithelial neoplasia in women. If you have decided to use photodynamic therapy for cervical and vaginal intraepithelial neoplasia in women, you can also choose not to participate in this study. This will not have any adverse effects on your access to conventional treatment.

[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. Qin Han at 13810632686; If you need to know about the participants' rights during the study, you can contact the Ethics Committee Office of Peking 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 (Efficacy and safety of photodynamic therapy for cervical and vaginal intraepithelial neoplasia:A multicenter prospective cohort study) , 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

_____