Effects of Antimicrobial Peptides Application after Non-surgical Periodontal Therapy on Treatment of Stage III and Grade B Periodontitis

The Medical Ethics Committee of Beijing Stomatological HospitalCapital Medical University approved the clinical study protocol(CMUSH-IRB-KJ-PJ-2018-03)

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Informed Consent Form

You are invited to participate in this study, and this informed consent form can help you decide whether to participate in this study. Before you agree to join this study, please read the following carefully and ask the researcher carefully if you do not understand anything or have questions.

1、 Purpose and Content

To evaluate the effects of the antimicrobial peptides (AMPs) as an adjunct to scaling and root planning (SRP) on clinical and microbiological outcomes in patients with periodontitis in Stage III and Grade B.

2、 Principal investigator: Yongmei Xie

3、 Research process

The expected number of participants in the study is 51 for one year. You will be randomly assigned to either minocycline hydrochloride or biologic antibacterial peptides. The group you will be included in will not be of your choice or assigned by your physician, but will be determined by random methods. The periodontal examination, subgingival plaque sample collection and periodontal cleaning and curettage will be performed by the professional periodontist of our hospital, and minocyclic hydrochloride or biological antibacterial polypeptide preparation will be applied locally. Both periodontal examination and sample collection are non-invasive operations. Periodontal curettage is the basic treatment for periodontitis, and it is a

painless debridement treatment when performed under local anesthesia. Individual studies take three months.

Pre-experimental: A clinical-radiographic examination was carried out to determine the periodontal status of the subjects. Fifty-one patients with periodontitis met the inclusion criteria volunteered to participate after they were detailed about the purpose, adverse reactions, and efficacy of the study. The patient participants were randomly assigned into the treatment group, Perio group, and SRP group, then supragingival scaling and oral hygiene education were performed to them (Fig.1).

Treatment: Seven days after the pre-experiment, the subjects were re-examined for periodontal clinical indicators recording and microbiological samples. After examination, subjects were assigned to receive one of the following treatments according to their groups: SRP group: only scaling and root planning, Perio group: scaling and root planning and subgingival application of minocycline hydrochloride ointment, or AMP group: scaling and root planning and subgingival application of antimicrobial peptide gel. The treatment was conducted by one experienced periodontist throughout the study.

Re-examination: At 7 and 90 days, microbiological samples were collected repeatly at the selected sites, and clinical examination was performed 90 days after treatment.

4、 Follow up

The study was followed up twice after the subgingival curettage, one week after the end of the subgingival curettage and the second time three months after the end of the subgingival curettage. Follow-up included: sample collection, periodontal examination and oral education. The total duration of your participation in this study is three months.

5、 Safety and adverse reactions

a. The drugs used in this study are all approved in China for the adjuvant treatment of clinical chronic periodontitis, purchased through the formal process of the hospital, with uniform concentration and purity, and widely used in the treatment of chronic periodontitis in the periodontal department of our hospital.

b. Periodontal examination and treatment in this study were all conducted by attending doctors with rich undergraduate clinical experience.

6、 Subject's rights and interests

Benefit:

a. Professional periodontist will make personalized periodontal treatment plan and periodontal treatment for you.

b. Get professional periodontal health education and maintenance.

If you decide to participate in the study, you should:

a. Follow up as planned, and do not stop scheduling appointments for treatment without first communicating with the study physician.

b. Antibacterial drugs and antibiotics should not be used locally in the oral cavity during the study period, and any other drugs used during the study period should be reported to your doctor, including over-the-counter drugs purchased by you. c. Tell your doctor if you have any health problems.

d. During the study period, oral hygiene should be maintained according to the oral hygiene maintenance methods taught by doctors

e. If you fail to comply with the terms listed above, you may not participate in the study.

Risk:

a. Periodontal examination and sample collection are non-invasive and have no adverse effects on your oral tissue and general health. All the drugs used have been approved for the treatment of clinical chronic periodontitis to ensure safety.

b. Periodontal treatment requires local anesthesia, which may result in the following complications: syncope, allergy, poisoning and hematoma. Please tell your doctor if you

have a history of drug allergy or general illness. If there are special circumstances, the doctor will terminate the treatment and the trial.

c. Common adverse reactions after subgingival curetting include pain and bleeding. The pain and bleeding can be relieved spontaneously within 24H after treatment. If the pain reaction is large, accompanied by systemic inflammatory reaction, systemic anti-inflammatory drugs should be taken. The trial was terminated.

Exit in the middle:

a. You may withdraw from the study at any time. If you cannot comply with the study plan, or if the doctor considers it for medical or other reasons, he or she may decide to withdraw you. If you withdraw from the study for any reason, the doctor will ask you to return to complete the final procedures of the study b. The research process may be terminated if:

Can not follow the time prescribed by the doctor
Oral topical application of antibacterial mouthwash or drugs during the study period

Confidentiality:

All records showing your name will be kept confidential. Your name will never appear in published reports.

Volunteer statement

a. I voluntarily agreed to participate in this study.

b. I have read and understood the risks set forth and described in this informed Consent.

c. I knew I could withdraw from the study at any time.

d. I have been given the opportunity to ask questions and I have understood the answers to all of them.

Subject's signature: Investigator's signature:

Date: