Patient Information Sheet

Project title: Ultrasound-guided pulsed radiofrequency versus dry needling for pain management in chronic neck and shoulder myofascial pain patients: a randomized controlled trial

Researcher's name: Dr. Jin Wang

Research location: Peking Union Medical College Hospital

Who and how to contact when there is an emergency or disorder associated with research:

Dr Jin Wang Tel. +86 15210424157

Dr Xulei Cui Tel. +86 13717739381

Sponsor for this research:

1. Bethune Charitable Foundation "Beien" Funding (bnmr-2021-009)
2. Peking Union Medical College Hospital High-level Hospital Clinical Research Funding (2022-PUMCH-B-007)

Project Background

Chronic myofascial pain is a common chronic pain disease that affects as many as 85% of the general population. Dry needling and pulsed radiofrequency are two effective treatment methods for chronic myofascial pain. Dry needling is the use of a thin needle to repeatedly puncture the pain region to alleviate muscle pain. Potential mechanisms may involve changes of local electrical activity and chemokines, as well as modulation of peripheral and central sensitization processes. Pulsed radiofrequency is the use of a needle-introduced electrode to generate an electronic field at the pain region, which will elicit an analgesic effect via neuromodulation. Both treatments have shown effective analgesic effects in the short term, however, there is currently lacking strong evidence on their median to long-term analgesic effects, and on which treatment shows better analgesic effect.

Objective

To compare the treatment effects of pulsed radiofrequency and dry needling in chronic neck, shoulder, and upper back myofascial pain patients.

Details to be treated with research participants

After receiving information about the project details, the participants sign the documents, and consent to participate in this research. Then, research assistants will conduct interviews to collect baseline information about the participants. The baseline information mainly includes the participants' age, gender, BMI, history of comorbid disease, characteristics of pain, medical scale scores on pain, emotion, sleep, and quality of life. After that,

participants will be randomized to one of the two treatment groups and receive corresponding treatment every week for four weeks. The treatment process conforms to routine clinical practice, and participation of the study will not bring additional risks. After completion of treatment, participants will come back for follow-up visits at 1, 3, and 6 months. During follow-up, the clinicians will re-evaluate the participants' pain, emotion, sleep, and quality of life status using the scales same as the baseline evaluation.

Benefits to the research participants

Participants will receive good postoperative follow-up and medical support during the follow-up period.

Side effects for the participants

This study does not bring any additional side effects other than that of the two treatments themselves. There may be minor hemorrhage, infection, and pneumothorax, but the likelihood of occurrence is low because the treatment will be provided by experienced clinicians under ultrasound guidance and strict sterilization. We will follow the routine clinical management protocol if any adverse event happens.

Confidentiality

The data will be collected with confidentiality. No name or number of hospital records will be collected. The data will be presented as a whole without individual identification. Only researchers will have access to information. This study will inform patients that they are in research and able to decide whether to join or not. Patients can withdraw from the research at any time and it does not affect the treatment of the patient in any way.

Informed Consent Form

Project title: Ultrasound-guided pulsed radiofrequency versus dry needling for pain management in chronic neck and shoulder myofascial pain patients: a randomized controlled trial

Researcher's name: Dr. Jin Wang

Name of research participant _____

Age _____ **Medical record number _____**

Research Participant Consent

I, Mr./Mrs./Ms. _____ have known the details of the research project as well as the benefits and the risks that will arise to me from the research clearly and consent to be involved in the above research project. And I know that if there is any problem or question I could ask the researchers. Also, I could quit this research project at any time, without affecting the treatment that I deserve. In addition, the researchers will keep the specific information about me confidential and will only disclose it in the form of a summary of the research. Disclosure of information about me to relevant agencies could only be done in cases of necessity for academic reasons.

Signed _____

Date _____

Description of the doctor or researcher

I have explained the details of the project as well as the benefits of research and the potential risks were known to the participants without any hidden objection.

Signed _____

Date _____