Department of Orthopaedics & Traumatology
The Chinese University of Hong Kong
香港中文大學矯形外科及創傷學系

Patient Information Sheet

"A Double-Blinded, Randomized-Controlled-Trial to Investigate the Effect of Pulsed Electromagnetic Field (PEMF) for Patients with Knee Osteoarthritis"

Introduction

You are invited to participate in a research study conducted by the Department of Orthopaedics and Traumatology at the Chinese University of Hong Kong. Degenerative musculoskeletal disorder such as osteoarthritis (OA) present a grand challenge with its high prevalence, and over 40% in the elderly suffered from Knee OA. OA is a debilitating progressive disease with typical symptoms such as acute pain causing loss of mobility.

Description of the study

Pulsed electromagnetic field (PEMF) treatment has shown to enhance cell activity related to tissue healing and give beneficial effects such as relief in pain, anti-inflammation and reduce swelling. This study aims to investigate the effectiveness of Pulsed electromagnetic field (PEMF) therapy on reducing knee pain for patients with knee OA. PEMF treatment may affect the metabolism, pain relief and muscle growth. In the reduction of knee pain, the knee function maybe improved, and even improving the quality of life.

Procedure

After screening, you will be randomly assigned to receive either a PEMF treatment or a sham treatment. You will be invited to attend 10-minute intervention sessions twice a week, for 8 weeks, fulfilling a total of 16 sessions. If you cannot attend the scheduled session, please notify in advance, and reschedule for a make-up session. The rescheduled session should be within the week of the missed session. The whole intervention programme has to be completed within 8 weeks.

You will be asked to complete questionnaires, muscle strength test, posture assessment in double leg squat and blood sampling for myokine and metabolites elevation before, at 1- and 2- months after the commencement of PEMF treatment, and at 3-, 6- and 12- months after finish the treatment. The whole intervention and assessment will not affect your existing medical care and rehabilitation.

Risks and Benefits

All of the treatment and assessments will be completed under the supervision of professional staff in CUHK and will be conducted according to standard procedures. In addition, in any case of unexpected or undesirable events, we will follow you closely and keep track of any pain or discomfort (including swelling, heat, and/or redness) after testing. If you experience any pain or discomfort during the testing, you are always allowed to stop the test immediately.

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Participation

Your participation is voluntary without any cost and no incentive will be provided for the participation; this means you can choose to withdraw at any time without giving any reason, without your medical care or legal rights being affected. You will only participate in one PEMF related study at a time. If you decide to take part in this research, please fill out and sign the consent form. Researcher will arrange assessment session for you. Please kindly arrive on time for your scheduled appointment. If you would like to reschedule the appointment, please contact the researcher as soon as possible.

Information Protection

Your personal information and data will only be accessed by the principal investigator, researchers involved in the study, and the regulatory authorities. If the results of the study are published, your identity will remain confidential. Blood samples will be stored in -80 ° freezer until the use for ELISA and other metabolites assays. The researcher will keep the information and samples collected for at least 5 years beyond the end of the study.

Contact person

If you have any inquiries about this study, please contact the principal investigator Professor Michael Tim Yun Ong at 26364171. You can also acquire your rights via The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee at 35053935.

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I,_____,HKID _____ consent to participate in the research project ''A Double-Blinded, Randomized-Controlled-Trial to Investigate the Effect of Pulsed Electromagnetic Field (PEMF) for Patients with Knee Osteoarthritis''.

I have read the consent form, understand that the procedure and risks involved and have received answers to any questions I asked. I understood the nature of this study and agree that the information collected will be kept by the researcher for at least **5 years** beyond the end of the study and blood samples collected will be kept in an established tissue bank at Prince of Wales Hospital. I understand that the data collected will be published to the public and in peer-reviewed scientific papers anonymously.

Signature: _____

Name: _____

Date: _____

Signature of person obtaining consent: _____

Name of person obtaining consent: _____

Date: _____

*If you have any inquiries, you can contact the following persons for more information:

Principal investigator: Professor Ong Michael Tim Yun Tel: 26364171

Joint CUHK-NTEC CREC Tel: 35053935