

Patient Information Sheet

'Vitamin D as an Intervention for Improving Quadriceps Muscle Strength in Patients after Anterior Cruciate Ligament Reconstruction: A Randomized Double-Blinded, Placebo-Controlled Clinical Trial'

Introduction

You are invited to participate in a research study conducted by Professor Michael Tim-Yun Ong from the Department of Orthopaedics and Traumatology at the Chinese University of Hong Kong. Anterior cruciate ligament (ACL) injury is a common sports injury and performing ACL reconstruction (ACLR) aims to restore knee function and facilitate a return to preinjury sports participation after an ACL tear. Yet, persistent quadriceps muscle loss can be seen in almost half the patients after ACLR and can persist beyond 12 months after surgery, affecting the recovery process.

Description of the study

Mechanisms involved in the causation of quadriceps muscle loss should be investigated in order to assist patients in achieving an ideal recovery after surgery. The purpose of the current study aims to investigate the relationship between Vitamin D supplements and Quadricep muscle strength after ACLR. Vitamin D deficiency can potentially result in unideal muscle strength regrowth in response to rehabilitation. Blood samples will be taken for further analysis to determine the possible association between serum Vitamin D levels and muscle atrophy.

Procedure

The duration of this study will be for one year. You will be invited to complete a set of questionnaires to evaluate your knee function, activity level, and a set of assessments regarding your muscle strength, volume and quality before surgery, 4-, 6-, 8-, and 12-month post-operation. A 16-week Vitamin D supplement course will begin at 4-month post-surgery. Your blood (5ml each) will be taken at pre-surgery, and 4-, 6-, 8-, 12-month post-surgery as well. The whole procedure will not interfere with your normal medical care or rehabilitation program.

Risks and Benefits

There may be potential risks during exercise, but they are relatively low. Please contact the responsible investigators if you feel any discomfort. There are no direct benefits involved in this study. However, the current study may lead to the potential development of adjuvant treatments for persistent muscle atrophy after ACLR.

Voluntary Participation

Your participation is voluntary; this means you can choose to withdraw at any time without negative consequences.

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. The researcher will keep the information collected for at least **3 years** beyond the end of the study and the tissues collected will be stored in an established tissue bank at the Prince of Wales Hospital.

Statement of Consent

I, _____ (full name), _____ (HKID) consent to participate in the study 'Vitamin D as an Intervention for Improving Quadriceps Muscle Strength in Patients after Anterior Cruciate Ligament Reconstruction: A Randomized Double-Blinded, Placebo-Controlled Clinical Trial'.

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 **3 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 paper anonymously.

Signature: _____

Name: _____

Date: _____

Signature of person obtaining consent: _____

Name of person obtaining consent: _____

Date: _____