Department of Imaging and Interventional Radiology

The Chinese University of Hong Kong

Consent Form

Title: High-resolution multi-parametric Magnetic Resonance Imaging for Focal Epilepsy

Document Date: 18 April 2024

NCT Number:

Department of Imaging and Interventional Radiology

The Chinese University of Hong Kong

Consent Form

Title: High-resolution multi-parametric Magnetic Resonance Imaging for Focal Epilepsy

Principal Investigator: Dr. HS Leung
Co-Investigators: Dr. Jill Abrigo, Dr. WH Hui, Dr. Billy MH Lai, Dr. Howan Leung, Dr. Xianlun Zhu, Prof. Winnie CW Chu

I declare that my participation in this study is entirely voluntary:

1. I fully understand and voluntarily join the research study.
2. I have already read the information sheet of this study and fully understand the details of the study including its aims, methods and use of data.
3. I have the right to ask any questions about the study and obtain satisfactory answers from the researchers/doctors.
4. I understand that I have the right to withdraw from the study and the healthcare personnel/researchers also have the right to ask my withdrawal due to inappropriate continuation of the study without affecting normal medical care.
5. All the information provided by me is correct and will be used for research purposes.
6. NTEC-CUHK Cluster REC/IRB will be one of the authorized parties to access the subjects' records related to the study for ethics review purpose.
7. I consent to undergo the proposed imaging examinations and further analysis in this study.

   I understand that magnetic resonance imaging (MRI) are safe imaging modalities, which have been applied in clinical practice for many years. Ultrasound and MRI do not involve ionizing radiation, while only non-ionizing radiation will be produced during scan. The whole process of scanning is painless. In this study, the standard safety guideline demanded for routine clinical ultrasound and MRI scan will be followed accordingly.

   I understand that the subjects undergoing MRI will hear knocking noise resulted from machine running once scan starts, hence ear plugs will be used for hearing protection. Occasionally, the subjects might feel warm because the radiofrequency wave can produce heat.

   I understand that, if the subjects feel any uncomfortable or hope to withdraw from ultrasound or MRI examination at any time during scan, they have the right to inform relevant staff to pause scan.

8. I consent to use my samples and data for research and/or clinical purposes, which include data acquired from imaging examinations and clinical record.
9. To benefit future research, all MRI scans from you will be deposited into the CUHK MRI Data Repository and share with CUHK collaborating partner(s) if necessary. For further analysis of your MRI data, your name will be removed from all scans. Only your gender, age, and disease status (if applied) at the time of scanning will be included.
10. I understand and accept that my personal data will be kept for five years after the study.
11. I agree that this consent shall remain valid even though the procedures set out in the information sheet may be re-scheduled from time to time.
12. I understand that, if I have any further questions, I can contact Dr. H S Leung at (852) 3505-1009 during office hours.
13. I understand that, if I have any questions about the ethical issue of this study, I can contact The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee at (852) 3505-3935.

Patient Name	
Signature	Date
Name of Guardian	Relationship of Guardian to patient
Signature of Guardian	Date

I give my informed consent to participate voluntarily in this research, the above information is true and correct to the best of my knowledge.

Researcher Name: _____

nature: _____

e: _____

Department of Imaging and Interventional Radiology

The Chinese University of Hong Kong

Patient Information Sheet

Title: High-resolution multi-parametric Magnetic Resonance Imaging for Focal Epilepsy

Principal Investigator: Dr. HS Leung
Co-Investigators: Dr. Jill Abrigo, Dr. WH Hui, Dr. Billy MH Lai, Dr. Howan Leung, Dr. Xianlun Zhu, Prof. Winnie CW Chu

Epilepsy is a disabling condition with repeated attacks of seizure. In a subset of patients, this is considered to be focal (i.e. originating from a specific part of the brain) where dedicated localization by seizure presentation, electroencephalography (EEG) and dedicated brain imaging including magnetic resonance imaging (MRI) is important to guiding the next step of management, including possible surgery to remove the seizure focus and achieving better seizure control. The localization of seizure focus on MRI is often difficult and could often be unrevealing on the first scan. We therefore aim to conduct study on the use of a dedicated high-resolution MRI scan and assess its feasibility in picking up more subtle lesions.

You are cordially invited to participate in our imaging study because:

- You received a diagnosis of epilepsy from neurologist and has suboptimal control on anti-epileptic medications.
- You has undergone previous investigation (clinical assessment, EEG or other imaging) which demonstrates possible focal epilepsy.
- You had previous MRI study which did not reveal any focal lesion.

Under this study, study patients will undergo a magnetic resonance imaging (MRI) examination in the Chinese University of Hong Kong Magnetic Resonance Imaging Center located in the Prince of Wales Hospital. MRI is an imaging modality based on magnetic field and

radiofrequency waves without involving any ionizing radiation, which has been applied in clinical practice for many years. The examination will last for 1 hour, and MRI contrast is usually not required. To date, no known side effects of MRI examination, or contrast medium have been reported if used appropriately, although the long term biological effects of MRI or its contrast agent on the human body are still not fully understood. Prior to MRI examination, you are required to sign a consent form. If you have any implants, devices or metallic materials in your body, you must inform our staff members as some of these implants/devices are not compatible with MRI examination or may alter the quality of the images. The contraindications to MRI will be checked prior to scan. The subjects with contraindication to MRI, such as bearing MRI-incompatible pacemakers, claustrophobia, pregnancy, will not be permitted to undergo MRI. During MRI scan, sounds of the machine are disturbing but you will be given a headphone for protection. Occasionally, the subjects might feel warm because the radiofrequency waves can produce heat. At any time during scan, the subjects have the right to inform relevant staff members to pause the examination, if they feel any uncomfortable or hope to withdraw from MRI scan.

Any adverse incident happened during the scan will be handled by following guidelines from Hospital Authority and CUHK. All examinations are free-of-charge within the scope of this study. Data collected will be used for research purposes and accessed by investigators and research personnel/students in this study only. Any information linking your identity and personal information will be kept confidentially. You have the right to withdraw from this study at any time and your participation is completely voluntary. The data and images acquired from this studies will be deposited into the CUHK MRI Data Repository and share with CUHK collaborating partner(s) if necessary, only after removal of identifiable personal data (such as name, HKID and Hospital authority file number).

Participation in this study is entirely voluntary, and will not affect your normal medical care. This study will be conducted in compliance with the research ethics guidelines from Hospital Authority and the Chinese University of Hong Kong and the Declaration of Helsinki. If you have any questions about this research study, please contact Dr. HS Leung at 3505 1009.