Information Sheet and Consent Form

Point-of-Care Ultrasound Screening for Thoracic Aortic Aneurysm in Hypertensive Patients in the Emergency Department

Principal Investigator: Professor Colin A. Graham

Institution: Accident and Emergency Medicine Academic Unit, Chinese University of Hong Kong

This informed consent form consists of two parts:

1. Information sheet (information about the research)
2. Certificate of consent (your signature certifies your agreement to participate)

You will be given a copy of the full informed consent form.

PART I: INFORMATION SHEET

This study is led by the Accident and Emergency Medicine Academic Unit of the Chinese University of Hong Kong, and we plan to recruit 952 patients within 12 months.

You are invited to participate in this study because you meet the inclusion criteria. Before you decide to participate, we encourage you to understand why this study is being conducted and what you can expect.

Please take the time to read the following information carefully and discuss it with your relatives or family doctor if you wish. Please feel free to contact us if you have any questions or would like to know more about the study.

Aim of the study

Thoracic aortic aneurysm (TAA) is the dilatation of the aortic wall that can progress to aortic dissection (AD), resulting in high mortality. In a previous study, researchers found that 7.5% of hypertensive patients in a clinic had an aortic diameter of ≥ 4.5 cm. We assume that patients presenting to the emergency department (ED) may have an even higher prevalence of dilated aortic diameter.

This study aims to evaluate the prevalence of TAA in the context of the ED by using point-of-care ultrasound (POCUS) to screen hypertensive patients.

Your participation

We would greatly appreciate your agreement to join our study. The investigator will perform a focused cardiac echocardiography using POCUS to measure the aortic diameter. The entire investigation will take approximately 15 minutes and should not cause you any discomfort. In addition to the POCUS examination, we will also collect your clinical data and ask you a few questions about your past medical history and family medical history. If we find concerning signs of an aortic aneurysm, we will inform your attending doctor and proceed with any necessary investigations. Your health is our top priority. All images and data will be stored for research purposes and auditing for 7 years after the conclusion of the study.

Cost and Benefit

There is no additional cost or reward for your participation in this study. Any incidental findings of aortic abnormalities will be reported to the attending physician.

Confidentiality and Privacy

We place great importance on your privacy. No personal information you provide will be published. This consent form will be stored separately from the data collection forms and ultrasound images to ensure confidentiality. Access to the data will be strictly limited to the researchers involved in this study. All data will be kept in a locked cabinet in the research office at Prince of Wales Hospital and will be destroyed 7 years after the completion of the study.

Under the laws of Hong Kong, specifically the Personal Data (Privacy) Ordinance, Cap 486, you have rights regarding the protection of your personal data, including its collection, custody, retention, management, use (including analysis and comparison), transfer in or out of Hong Kong, non-disclosure, and erasure.

For any queries, you may consult the Privacy Commissioner for Personal Data or their officer at 2827 2827 to ensure your understanding of the significance of compliance with privacy laws.

By signing the written informed consent form, you authorize the Research Ethics Committee (REC) and regulatory authorities to have direct access to your study data for verification purposes.

What if you want to drop out of the study?

Participation in this study is entirely voluntary. You may withdraw your consent at any time and request that we do not use your data. Please be assured that we will provide the best possible care regardless of your decision to participate. If you choose not to enter the study, you will still receive appropriate treatment as determined by your clinician.

Enquiry

You can contact the research team responsible for the study for further information at 3505 1698 for further information.

You may also contact the independent body, the New Territories East Cluster Research Ethics Committee, at 3505 3935.

PART II: CERTIFICATE OF CONSENT

Point-of-Care Ultrasound Screening for Thoracic Aortic Aneurysm in Hypertensive Patients in the Emergency Department

I have read the INFORMATION SHEET, and the study has been explained to me. I understand all the benefits and risks associated with this study. I have had the opportunity to ask questions, and all my questions have been satisfactorily answered. I have received sufficient information about the study.

If my participation in this study results in any physical injury or emotional discomfort, the investigator will treat me or refer me for treatment. I understand that I am not giving up any of my legal rights by signing this form.

By signing this informed consent form, I certify that all information provided is true and correct. I understand that I am free to withdraw from the study at any time without having to provide a reason, and that my withdrawal will not affect my current or future medical care.

I understand that my identity will be kept confidential. I agree to authorize the Research Ethics Committee (REC) and the regulatory authorities to have direct access to my research data for the verification of clinical trial data, without violating my confidentiality, to the extent permitted by applicable laws and regulations.

1. I hereby consent to participate in this research study and grant permission to obtain echocardiographic images and clinical data from me.
   Yes ☐ No ☐

2. I hereby consent to the sharing of my data for related studies.
   Yes ☐ No ☐

Name of patient/next of kin	Signature	Date
Name of witness	Signature	Date
Name of investigator or research assistant	Signature	Date