Prospective Register Of patients undergoing repeated OFfice and Ambulatory Blood Pressure Monitoring (PROOF-ABPM)

Participant information Sheet V2_24.03.2015

REC reference: 15/SC/0184

We would like to invite you to take part in a research study. This information sheet explains why the research is being conducted and what it will involve if you decide to take part. If you have any questions, please do not hesitate to ask.

What is the purpose of this study?

The purpose of this study is to understand the association between blood pressure and diseases such as heart attack and stroke. Accurate measurement of blood pressure is essential to ensure that patients at risk of disease receive the right treatment and care. Blood pressure measurements can be taken in the doctor's clinic, at home by a patient or automatically over a period of 12-24 hours (ambulatory monitoring). Depending on the method of measurement, blood pressure level will vary. We would like to better understand this variation by studying blood pressure readings taken in 1000 patients, in different settings and using different methods. We hope this information will permit more accurate blood pressure measurement in the future, improving the quality of patient care.

Why have I been chosen?

You have been chosen because you have, or are about to undergo blood pressure monitoring as recommended by your doctor or nurse.

What will happen to me if I take part?

If you decide you would like to take part you will need to agree to let us store your personal information (name, address, date of birth, NHS number) and link it to information about your blood pressure and medical history. We will also share your identifiable information with the NHS Health and Social Care Information Service to allow us to follow your health status in the future. We will not share identifiable information with any other parties. **You will not be expected to undergo any additional tests if you participate in this study.**

How will my medical records be handled?

All information about you will be handled in the strictest confidence. It will be stored securely on a password protected computer and only the research team will be able to access the information. All data will be kept securely according to the Data Protection Act 1998. Relevant **identifiable Information** (your name, date of birth, address, NHS number) will only be shared with the Department of Health National data centre (Health and Social Care Information Service; www.hscic.gov.uk) to allow us to collect information about the state of your health in the future. We will not share this information with any other parties.

Do I have to take part?

No, this is a voluntary study, it is your decision. If you decide not to take part, or if you agree but later change your mind, you will still receive the same standard of medical care. **You can withdraw or leave the study at**

any time without giving us a reason. Should you wish to withdraw, please let us know if we can keep the information we have already collected about you.

What are the possible benefits or disadvantages of taking part?

This is an observational study, so participants will receive all their usual care as normal. Other than the time taken to understand the study, and give consent, we do not anticipate any disadvantage from taking part. If you do take part it will help others in the future by enabling us to find better ways to identify and care for people with raised blood pressure.

Will my taking part in this study be kept confidential?

Yes. Responsible members of the University of Oxford (and the appropriate NHS Trust) may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations. We may share anonymised data with other researchers to support future research.

What will happen to the results of the study?

The results will be published in a scientific journal/s and summarised on our website (http://www.phctrials.ox.ac.uk/studies/proof-abpm) for you to read.

Who has approved this study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the NRES Committee South Central - Oxford A (REC ref: 15/SC/0184).

Who is organising and funding the research?

This research is being funded by the Medical Research Council. The study is being coordinated by the Nuffield Department of Primary Care Health Sciences at the University of Oxford. The sponsor of the study is the University of Oxford.

What if something goes wrong?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of any clinical treatment provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study you should contact the study chief investigator (Dr James Sheppard) or the University of Oxford Clinical Trials and Research Governance office (01865 572224, ctrg@admin.ox.ac.uk).

Who can I contact for further information?

If you have any further questions, please contact the Chief Investigator, Dr James Sheppard:

Dr James Sheppard, Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Observatory Quarter, Woodstock road, Oxford, OX2 6GG.

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