Frequently Asked Questions for patients participating in the trial

The information below is about the IMPROVE trial (a research study) that you very kindly agreed to take part in when you underwent repair for your ruptured aortic aneurysm.

UPDATE & THANK YOU:

Between September 2009 and July 2013, 613 patients from 30 vascular centres participated in the trial and they were randomly allocated to receive either an endovascular repair (EVAR) or open repair to repair their aorta.

After leaving the hospital, patients had hospital assessments and were asked to complete follow-up questionnaires about their health status at approximately 3-months, 12-months and 3-years following their aneurysm repair, which were completed by ~80% of the patients at each time point. Patient follow-up ended in July 2016 and we are now working on data analysis. .

We are extremely grateful for the high response rate to the follow-up questionnaires and the many positive comments received.

What are my rights as a research participant?

You are under no obligation to continue in the study and you may withdraw any time without giving a reason. If you withdraw from the study, your care will not be compromised and you will be offered standard follow-up. You can notify your decision to withdraw and discuss your wishes (e.g. whether you would like no further contact, etc.) with either your local Principal Investigator/coordinator or with national trial office personnel in London (contact details at the end of this document).

In addition, you have the right to be given new information about the study. You have the right to ask questions at any time and have them answered as soon as possible. You also have the responsibility to stay informed during your participation in a study. You should ask questions about anything you do not understand or simply want to know.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the trial will be kept confidential. Your medical data will be coded with a numeric Trial ID and only authorised researchers who are directly involved in the project will have access to your identity. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

When you gave consent for the trial, you had agreed for some parts of your medical records and the data collected for the study to be looked at by authorised persons from the team organising the research at Imperial College London, as well as representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly.

In addition, you had agreed for the trial team to obtain further information about your health status from NHS Information Centre and NHS Central Register. There have been a number of organisational changes and both bodies are now included in **NHS Digital**. We provide your NHS number and date of birth to the NHS Digital team to receive information to cross-check the number of additional procedures you may have undergone following your emergency aneurysm repair, so that we have accurate information about further treatments, even if you have moved or are treated at a different hospital.

What happens to my data?

Anonymous data from your medical records is recorded on data collection forms by authorised personnel at Imperial College London and at participating NHS Trusts (Chief Investigator and Trial Manager, local Principal Investigators and coordinators). Data collection forms (which you can view within "Essential Documents" section of our websites) have your unique Trial ID and never use your name or NHS number. These anonymised data will be kept for 10 years after the end of the study to conform with the regulations for safeguarding clinical trial data.

The trial also uses routine NHS data, which is received from NHS Digital, to check that we have not missed any hospital admissions or treatments related to your earlier aneurysm repair. If we identify

any "missed admissions /treatments", we cross-check these with the relevant hospital and then complete the necessary data collection form. The data received from NHS Digital may contain identifiable information and are stored electronically with military level of data security at the offices of the Vascular Surgery Research Group in Room 4N12 at Charing Cross Hospital (Imperial College Healthcare NHS Trust). This non-networked computer is accessible only to the Trial Manager (Dr Pinar Ulug) and the Chief Investigator (Professor Janet T. Powell). All patient data received from NHS Digital will be destroyed securely by 31st January 2017.

What happens when the study is over?

The research team start checking and analysing the data that were collected from all patients throughout the study. Findings and data collected about you will be compared to other participants. The primary outcome of this trial is patient survival, but we also are interested in the costs related to your original aneurysm repair (including all hospital treatments relating to the aneurysm and its repair) and your quality of life for up to 3 years after your aneurysm burst. The trial management committee, which includes specialists in clinical trials, vascular surgery, statistics and health economics will conduct the analysis and report the findings to scientific meetings and medical journals and provide summaries of the data for patients on our trial web sites: your local hospital also will send you the summary for patients in a letter. The results will also be shared with experts and various government agencies responsible for the provision of services in the NHS (e.g. NICE).

When will the patients participating in the trial know the results?

Early results became available in 2014 and were shared with patients participating in the trial. We expect late results to become available in early 2017. Your local hospital will write to you at that time and the results will be available on the trial web sites below: www.imperial.ac.uk/medicine/improvetrial

or

www.improvetrial.org

Who has reviewed this study (the IMPROVE trial)?

The study has received a favourable ethical opinion for conduct by the South Central – Berkshire Research Ethics Committee (previously Berkshire Research Ethics Committee; Reference number**: 08/H0505/173;** 02071048043), the Scotland A Research Ethics Committee (Reference number: **08/MRE00/90;** 0131 465 5680) and in Canada from University of Western Ontario Health Sciences Research Ethics Board (Reference number: 17698). This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme (**project number 07/37/64**)

There also is an oversight committee appointed by the NIHR to ensure patient safety and that the trial is run properly and to the highest standards.

What if something goes wrong?

Imperial College London (the trial Sponsor) holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator (Professor Janet T. Powell; j.powell@imperial.ac.uk; 020 3311 7312) and local Principal Investigator, whose contact details would have been listed on previous communication you received about the trial (If you don't know your local Principal Investigator and would like to find out, you can email improvetrial@imperial.ac.uk). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Joint Research Office (jointresearchoffice@imperial.ac.uk; 020 7594 9459).

Further information

If you have any questions that are not answered above or if there is anything you would like to discuss concerning your participation, you can either contact the local investigators at the hospital where you had your aneurysm repaired or you can get in touch with the trial coordinating centre via the details provided below:

Chief Investigator: **Professor Janet Powell** Telephone: 020 3311 7312

Trial Manager: **Dr Pinar Ulug** Telephone: 020 3311 7307

Postal address:

Vascular Surgery Research Group, Room 4N12, 4th Floor North Wing, Imperial College London at Charing Cross Hospital, Fulham Palace Road, London W6 8RF

Trial Websites& Twitter page:

You can read more about the trial and latest updates via below:

www.imperial.ac.uk/medicine/improvetrial

www.improvetrial.org

@IMPROVETrial

ClinicalTrials.gov Identifier: NTC00746122 www.clinicaltrials.gov