



INFORMATION SHEET: The RATPAC Trial

A trial of rapid blood testing for acute chest pain

ANYTOWN Hospital is one of six hospitals taking part in the RATPAC research study. You are being invited to take part in this study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Why is this research study being done?

The aim of the RATPAC study is to find out whether a new blood test improves the care of people coming to hospital with chest pain. The new test uses two blood samples, taken an hour and a half apart, to find if there is any evidence of heart damage. Current blood tests for heart damage are not fully accurate until 12 hours after the episode of chest pain, so if patients need these tests they usually have to be admitted to hospital. It is hoped that the new blood tests will reduce the need for patients to be admitted to hospital.

Why am I being asked to take part?

You have attended the hospital after an episode of chest pain or similar symptoms.

What does the research involve?

If you agree to take part you will be allocated to either receive the new blood test or to receive standard care without the new blood test. This allocation will be done by a random process, rather like tossing a coin. If you are allocated to receive the new blood test you will be asked to provide two blood samples 90 minutes apart. The doctor or nurse will then use the results of these tests to decide what care you need. If you are allocated to receive standard care without the new blood test then the doctor or nurse will advise you what tests you will need. This may involve blood testing and/or admission to hospital. Apart from the new blood tests, your care will be just the same as for other patients attending with similar symptoms at this hospital.

We will send you a postal questionnaire in one month's time. This will ask you what you thought of your care, how your health has been, and what health services you have used. It would be useful if you made a note of any services you may have used once you are home. A second questionnaire in three months time will again ask you how your health has been and what health services you have used. After this your involvement in the trial will end. Each questionnaire will take about fifteen minutes to complete.

We will examine your hospital records to find out what happens to you after your assessment. We will then compare the two groups of patients in the research study (those who received the new test and those who did not) to find out whether the new blood tests improved patient care.

What will happen to information recorded about me?

The information recorded about you will be kept on computer files in the University of Sheffield. It will only be seen by the Research Team and regulatory authorities. It will not be passed on to the Hospital, your General Practitioner, or anyone else. We will inform your General Practitioner that you are taking part in this study but we will not pass on any of the information you give us without your consent.

What will happen to any blood samples I provide?

If you provide any blood samples, either for the new blood test or for any other tests requested by the doctor or nurse, these will be used by the doctor/nurse to help diagnose the cause of your symptoms. If there is any blood remaining after these tests it will be stored and sent to St George's Hospital in London. It will then be used by the Research Team to test experimental new blood tests for diagnosing chest pain. We will not use these samples to test for anything that does not directly relate to diagnosing chest pain. So we will not identify anything from your blood sample that may be relevant to you in the future.

What if I do not want to take part in the study?

It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason, simply phone or email the research team on the contact details below. You do not have to give an explanation for not taking part. A decision to withdraw at any time, or a decision not to take part, will not affect any health care you may need.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (contact details below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or from the research team.

In the unlikely event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Sheffield or *ANYTOWN* Hospital but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who is undertaking this research?

This project is being carried out by researchers from the Medical Care Research Unit, at the University of Sheffield. This is an independent research unit that has a long history of undertaking research into the National Health Service. The research has the required ethical approval from the Leeds East Research Ethics Committee.

Who is funding the research?

The project is funded by the National Institute for Health Research Health Technology Assessment Programme (NIHRHTA).

What will happen to the results of the study?

We will publish the results in a scientific journal and produce a report that is freely available to anyone who wishes to read it. You will not be personally identified in any report or publication we produce. Please contact us using the details below if you would like to see a summary of the results when the trial is completed.

Who can I contact if I need more information?

If you would like any further information about this project please contact:

Liz Cross, RATPAC Trial Manager

Medical Care Research Unit, ScHARR, University of Sheffield

Telephone: 0114 222 0762 or email: e.a.cross@sheffield.ac.uk

Study website: www.sheffield.ac.uk/chestpain

Please keep this information sheet