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# Participant Information Sheet

**Randomised controlled trial comparing molecular Point-of-Care testing for gastrointestinal pathogens with standard clinical care, in adults presenting to secondary care with suspected infectious gastroenteritis: a pilot study (GastroPOC Trial).**

**Chief Investigator: Dr Tristan Clark** BM MRCP DTM&H MD,Associate Professor and Honorary Consultant in Infectious Diseases.

**Research Study**

You are being invited to take part in the research study named above. Before you decide if you want to take part, 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. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

**What is the purpose of this study?**

Gastroenteritis (vomiting and diarrhoea) leads to a large number of visits to emergency departments and admissions to hospitals in the UK. Detection of the specific infection that causes gastroenteritis can take several days with current tests. If these tests find a particular infection, or not, it may alter which treatments are offered (such as antibiotics), or the place in which that the patient is cared for (such as a side room).

A rapid ‘point-of-care’ test for infections that cause diarrhoea and/or vomiting has been developed and can provide accurate results in 1 hour rather than several days.

We wish to tests if using this test improves patient care.

**Why have I been asked?**

The symptoms and clinical signs that you display are consistent with gastroenteritis (including diarrhoea and/or vomiting) so we would like to potentially test you for a wide variety of infections that might have caused your illness.

We are therefore asking for volunteers over the age of 18 who have come to hospital with diarrhoea, to take part in this study.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will receive a copy of your consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**What will happen to me if I take part?**

After you have finishing reading this, you will have the opportunity to discuss the study in more detail with a member of the research team. If you are happy to take part, then you will be asked to read and sign a consent form. Certain details will be briefly asked of you, including what symptoms you have had.

A computer program will then assign you randomly to Group One or Group Two. Group allocation is completely random: neither the research team nor anyone else can influence into which group you are placed. Those in Group One will have a rapid point-of-care test as soon as possible, those in Group Two will not, but a sample is still requested from them.

For those allocated to Group One: you will be asked to provide a stool sample. If you cannot do this you will have a rectal (back passage) swab taken by the research staff. The swab is like a ‘cotton bud’. We will then come back later to collect a stool sample as soon as you can provide one.

The sample from you is then taken to be analysed for many different infectious causes of diarrhoea and/or vomiting. You will be informed of the results, as will the doctors and nurses looking after you. You have the right to discuss the results with the research team and the clinical team looking after you.

For those allocated to Group Two: you will receive standard care from the doctors looking after you which may include sending a stool sample to the laboratory for testing. The research team will ask you to provide a stool sample but if you are unable to provide this we can take a rectal swab instead. We will then come back later to collect a stool sample as soon as you can provide one. These will be stored and tested later, likely long after you have been discharged. You will not be informed of the results as it will not affect the care you receive.

For all patients (those in Group One and Two)

You may be asked for another stool sample, rectal swab and/or a vomit sample and/or a blood sample (taking about one and half tablespoons of blood) for additional ethically approved research. You have the right to decline all or any of these further tests, should you wish, and this does not affect you being part of this study or the care you receive. These samples would be taken on the day you are enrolled in the study, or if necessary, the day after. The flow chart at the end of this document summarises all that you may be involved in.

In addition we may ask you to fill in a form regarding your satisfaction with the care and the tests you have received. The form is based on questions from the Care Quality Commission’s survey (the organisation which monitors and inspects the NHS). Filling in this survey is entirely optional, and will happen on the day you are discharged from hospital. A member of research staff may help you fill this in if you wish.

Once you have been discharged, regardless of which group you are in, a researcher will look at your hospital case notes to determine if having the test performed, or not, has affected your management during your hospital stay. This includes how quickly you were discharged, if you were put into a side room or not, and what antibiotics you received, if any.

**What about confidentiality?**

We take participant confidentiality very seriously. Only a very limited amount of personal identifiable information is requested from you, and when we come to look at and publish any results then information is presented anonymously – i.e. your details and personal information are never made available.

With your permission, your GP will be informed that you are participating in this study, but no further information is given to them. The doctors and nurses treating you are told the results of the test for those in Group One (who will have the test as soon as possible).

**What are the risks?**

For those that have one taken, the risks of having a simple swab taken from your rectum (back passage) are minimal. Having the swab taken could be mildly uncomfortable for some people, but it is over very quickly.

**What happens when the research study stops?**

Initially we are carrying out an initial ‘pilot study’ (this study). This will end when we have recruited 200 people like you. By this time we hope to have collected all the information we need to decide if we can go on to test a lot more people. The samples collected during the study are stored without any of your details on them and are only used in further research into infectious diseases under the direction of the chief investigator of this study.

**What will happen to the results of the research study?**

We intend to publish the results of our research in medical journals and to present the results at scientific meetings. The information from these journals may be available on the internet. All results are anonymous in these publications or presentations. We would like any useful results to form the basis of other studies looking at this and also change how medical professionals treat patients for the better.

**Who is organising and funding this research?**

Money from the NHS and the University of Southampton is funding this research. The company who manufacture the equipment and test kits used in this study have provided them to us for free but have not been involved in the design of the study and will not be involved in the conduct of the study or the analysis and presentation of the results.

**Who has approved this study?**

The Health Research Authority, including an ethics committee, has reviewed the design of this study and approved it to go ahead. The local NHS Research and Development department has approved this study too.

**Who can I talk to further?**

The research team are very happy to answer your questions and discuss things further with you. You are welcome to talk to your doctors and nurses, family and friends, should you wish, about participating. Should you have any specific concerns you are welcome to discuss these with a research doctor, or the chief investigator, or Patient Support Services, about how you might take your concerns further.

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Decide whether or not to take part after reading this information sheet

Agree to take part & sign consent form

Random allocation of group

Group 1

Group 2

Stool sample (or rectal swab\*) taken and run on rapid analyser for infections

You and your doctors and nurses will be told of the results within a few hours

You may decide not to take part

All patients will receive standard NHS laboratory tests on their stool if the doctors looking after them think it is needed.

For all patients we may ask for the following additional samples (entirely optional: it does not affect you being in the study if you decline all or any of these): another stool sample/rectal swab, a vomit sample (if vomiting) and a blood sample. All these research samples would be taken on the day that you are recruited to the study or the day after. You may also be asked to complete a patient survey on the day that you are discharged from hospital. There are no follow up visits in this study; information is collected from your medical records after your illness is over.

Stool sample (or rectal swab\*) taken and frozen for testing by research team at a later date. You and your doctors and nurses will not receive the results from the research sample

\*The best sample to run is a stool sample but we can take a rectal swab if you cannot give us a stool sample promptly, and we shall collect a stool sample later on

Receive rapid stool test in addition to standard NHS care

Receive standard NHS care

What happens if I choose to take part?