Multi-centre EuRopean study of MAjor Infectious Disease Syndromes – Acute Respiratory Infections (MERMAIDS-ARI) Study

Information Sheet for Consultee

You will know from talking with the doctor that your relative, friend, or person you are representing has a serious respiratory infection. This must be an extremely anxious time for you. We would however be grateful if you would take a little time to read this information. The person you are representing is taking part in a research study and we would like you to understand what the study is about. We'd like to ask your opinion whether or not they would want to continue being involved. Please consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative, friend, or person you are representing should be withdrawn.

If you are unsure about taking the role of consultee you may seek independent advice.

What is the purpose of the study?

The Platform for European Preparedness Against (Re-)emerging Epidemics (PREPARE) is a European network set up to improve research about infectious diseases and emerging infections across Europe. The overall aim is to improve European preparedness for emerging infections and research into medical management and treatments to control future outbreaks. For more information visit: www.prepare-europe.eu.

The Multi-centre EuRopean study of MAjor Infectious Disease Syndromes (MERMAIDS) is part of the PREPARE research. This study is looking at acute (recent onset) respiratory (nose, throat and chest) infections, one of the most common infectious diseases across Europe. The study involves a comparison between adults who visit their GP due to respiratory infections and adults who need hospitalisation for similar infections. This will allow us to study why some people develop more severe symptoms. The results of this study can help us to improve the prevention, treatment and care of these infections and hopefully reduce the number of severe cases.

Respiratory infections such as colds, flu (influenza), and pneumonia affect millions of people around the world every year. Most cases are mild, but some people become very unwell. There is a great deal that we still do not understand about why some people become more unwell than others, including the role of pre-existing health conditions (such as diabetes or heart problems) and the effect of in-born abilities to fight infections.

Our genes (genetic material or DNA) provide the biological instructions that tell our cells how to work. Some of these genes are involved in protecting us from infections and, like other genes such as those for hair colour, different people have different versions of these genes.

In order to determine how people respond to respiratory infections we are collecting nose swabs and blood samples to determine what kind of organism is causing the infection and to look at the functioning of the genes that are involved in protecting people from infection. We will be looking to see if there are differences in the way the genes are functioning between groups of patients with different pre-existing health conditions, e.g. heart disease or lung disease, and also to look at differences between individuals who develop severe infection rather than a mild infection. This information will help inform research into better treatments and prevention in the future.

Why am I being asked to consider the study?

The person you are representing has already agreed to take part in this research study but now that they are very unwell we cannot be sure that they would want us to continue to collect the nose swabs and blood samples for the study. We are, therefore, approaching you (someone who has their welfare and best interests in mind), to confirm that you know of no reason why they would not want us to continue collecting the study samples.

Declining to allow us to collect the study samples will not affect the standard of care they receive.

Do I have to make a decision?

The person you are representing has already given their consent to participate in the study but has subsequently become seriously ill and consequently lost capacity. In law, this means that their prior consent is no longer valid and we have to consult with someone who knows them well and who can give us advice about whether they would wish to continue in the study. We are asking you to think about the wishes of the person you are representing and inform us if you think they would wish to continue in the study.

Before you consider this, it is important for you to understand what the research involves for the participant. Please take time to read the rest of this information. One of our team will go through the information with you. Please ask us if there is anything that is not clear or if you would like more information and time to consider. Any objections you make will not affect the participant's care or treatment in any way.

We will describe the study and go through this information sheet with you, which we will then give to you. If, after consideration, that the person you are representing would have wanted us to continue to collecting study samples we will ask you to sign a form to confirm this and provide you with a copy.

If you (or the participant when/if they regain capacity), change your mind, they can be withdrawn from the study at any time. If you do change your mind, this will not adversely affect their care. The participants (and their doctors) who take part in this study are not paid to do so and participate freely.

What does the study involve?

Much of the information and the samples that we require for the study will already be collected as part of routine care. If you agree that the person you are representing would

want to remain in the study then you will be giving us permission to obtain extra or leftover portions of any samples of respiratory secretions that are taken for their normal care. You also give us permission to access information about their health and the results of any tests conducted during this hospital admission. This includes information about pre-existing health conditions, treatments given and diagnostic results.

There are some samples that we will need to obtain specifically for this study. If you agree that the person you are representing would want to continue in the study a doctor or nurse may take two swabs from the back of their nose on their third day in hospital and again on the day they are discharged. These will be used to determine the type(s) of viruses or bacteria that are causing their infection and to learn more about them.

The nose swabs are a routine and usually painless procedure however they may cause the patient to gag a little bit or make their eyes water. It will take about 3-5 minutes for the doctor or nurse to collect both nose swabs.

We will also need specific blood samples taken for the research analysis on their third day in hospital and on the day they are discharged from hospital. The extra blood collected will be at most 15mls (about 3 teaspoons) on any day. The blood sample will be collected using standard venous blood sampling techniques and be carried out by a nurse or doctor. Every effort will be made to collect the research blood at the same time as blood is being drawn as part of routine hospital care.

Four weeks (28 days) after the date of the hospital admission of the person you are representing there will be a final study follow up visit. By this time we expect they will have regained the ability to make decisions for themselves. We will either ask them to return to the hospital, visit their GP or a nurse may visit them at home or at work. During this visit they will be asked some questions about their health and any medications they have been taking and the doctor or nurse will collect a blood sample.

Are patient details kept confidential?

Yes. Some parts of their medical records may be looked at by authorised members of the research team and authorised people checking that the study is being carried out correctly. The information collected for the study will be stored securely in electronic systems with no personal identifiers attached (such as name or address) and to which only authorised personnel will have access. We have already collected their personal contact details to gather some follow-up information for the study. We will keep their personal information confidential and will not pass this on to the University of Oxford. This contact information will be kept by the local research team and as soon as the information has been gathered their contact details will be de-identified. The local research team will store the de-identified research data and any research documents with personal information, such as consent forms, securely at your local NHS site, in accordance with local policies, after the end of the study.

What will happen to the samples and information?

We will be using information from the person you are representing and from their medical records in order to undertake this study and the University of Oxford will act as the data

controller. This means that we are responsible for looking after your information and using it properly. Data protection regulation requires that we state the legal basis for processing information about them. In the case of research, this is 'a task in the public interest.'

Rights to access, change or move their information are limited, as we need to manage information in specific ways in order for the research to be reliable and accurate. If you (or the person, if they regain capacity) wish them to be withdrawn from the study, we will keep the information that we have already obtained. To safeguard their rights, we will use the minimum personally-identifiable information possible. Further information about their rights with respect to their personal data is available at

https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use information from the research team by contacting mermaids-ari@ndm.ox.ac.uk.

The blood samples and nose swabs will be sent with a unique identification code to the central study laboratories in Belgium and the Netherlands where they will be analysed. Neither the person you are representing nor their doctor will be informed of the results of these tests, they will only be used to inform the research. The samples will be used to diagnose which viruses or bacteria caused the infection and we will use the blood samples to look at how the body fights the infection. All of the study samples will provide very valuable information so even if their doctor was not able to determine the cause of the infection we will still keep and test their samples. We may also use the blood sample to analyse their DNA. We may compare their DNA together with DNA from many other people to try to find out what makes some people more likely to get a more severe infection. This will be done confidentially and the results cannot be linked back to them.

The samples will also be stored, completely de-identified, in a biobank run by the PREPARE group. A biobank is a secure cold-storage facility for human blood and tissue samples. This is done so that in the future we can make further investigations into treatments for respiratory infections, to help prepare and respond to new and existing infectious diseases causing outbreaks in Europe. Any future research will only be carried out once it has been ethically approved. The person you are representing will not be told about further tests done to the samples and no information can be linked back to them as all samples will be stored de-identified.

Are there any benefits to taking part in this study?

There is no direct personal benefit to the person you are representing. However, the information we learn from this study can help provide valuable information into medical management, treatment and research into infectious diseases with epidemic potential in the future.

What are the risks of taking part in the study?

Since this is an observational study (we are not giving you any new or experimental drugs or treatments) we do not see any risk in taking part. The person you are representing may experience some discomfort when the nose samples are collected. During the blood taking they might feel some slight pain and light-headedness and there might be a risk of local bruising from the needle stick.

If DNA testing is done it will be carried out anonymously and results will never be linked back to them. Neither the person you are representing nor their doctor will be informed of any DNA test results, these results will be used for general research purposes only.

Expenses and Payments

The person you are representing has been offered a £50 gift card to compensate them for the time they have invested in attending all of the study visits. They will receive the gift card after the day 28 visit has been completed.

Who is organising and funding the research?

The research has been organised by the Epidemic Diseases Research Group at the University of Oxford, UK and is being funded by the European Commission. This study is funded as part of the PREPARE programme of research. As we are working with PREPARE the results from this study will be shared with the partners of this group, but your information will always be kept confidential.

What happens once the study has stopped?

Once the person you are representing has finished the study, after the final 4-week follow up appointment, there is no need for any further information.

What if there is a problem?

If you have any queries about this study then please contact the study co-ordinator Insert local co-ordinator details.

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 firstly contact the study co-ordinator on the details above or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on +44 (0)1865 616480 or the head of CTRG on E-mail: ctrg@admin.ox.ac.uk

University of Oxford, as research sponsor of the study has insurance in place to provide for any unexpected harm arising from participation in the study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment with which the person you are representing is provided.

What will happen to the results of the research study?

We will publish the results in scientific journals and present them at scientific meetings. The details of the person you are representing will remain strictly confidential, with no personal information being included in any publications.

Who has reviewed the study?

All research in the NHS is looked at in detail by an independent group of people called a Research Ethics Committee, who protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the NRES Committee: West Midlands - The Black Country REC Number: 15/WM/0254

Thank you for taking the time to read this information sheet

Further information and contact detail:

Insert details

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