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

Secondary Care Patient Information Sheet

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 to undertake research into the care and treatment of these infections 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.

Before you decide if you want to support this research by taking part in this study, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information carefully. One of our team will also go through the information with you. Please ask us if there is anything that is not clear or if you would like more information. Your decision is completely voluntary and will not affect your care or treatment in any way.

What is the study about?

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 will take two swabs of the back of your nose and some 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 you 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 have I been invited to take part?

We are inviting people who have been admitted to hospital due to a respiratory infection to take part and your doctor has assessed that you are eligible to take part. We are planning to recruit a total of 2,000 volunteers from across Europe.

Do I have to take part?

No. It is your decision whether to be part of this study. Even if you decide to take part you are free to withdraw at any time without a reason and without it affecting the standard of care you receive in any way. If you wish to withdraw from the study please contact the study team using the contact details on the last page.

What will happen if I take part in this study?

Once your doctor or nurse have assessed that you are eligible to participate and you have read this information leaflet, and have discussed any questions you might have, you may decide that you are happy to take part in this study.

You will then be asked to sign a written consent form to say that you are voluntarily taking part in the study and that you understand what is involved. If you are in an isolated room as a precaution to guard others against possible infection, information about the study would have been given to you verbally and your agreement to take part in the study will be recorded in your medical notes. You can still withdraw from the study at any time without any reason and without it affecting your care in anyway.

Much of the information and the samples that we require for the study will already be collected as part of your routine care. If you consent to participate 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 your normal care. You also give us permission to access information about your 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. In the unlikely event that you become more seriously unwell due to your respiratory infection and are temporarily unable to make decisions for yourself during the study period we would like your permission to continue to access your medical information and to collect study samples during this time. This is an optional decision and you are free to decline. If this occurs we will consult a relative, friend, or person representing you to consider your wishes and feelings. They will be given the opportunity to object to your further participation in the study and you can be withdrawn from the study at any time. Therefore it is important for you to discuss your participation in this study with a relative, friend, or representative prior to agreeing to take part.

There are some samples that we will need to obtain specifically for this study. After you consent to take part in the study, and within 24 hours of your hospital admission, a doctor or nurse will take two swabs from the back of your nose. For the nose swabs you will need to tilt

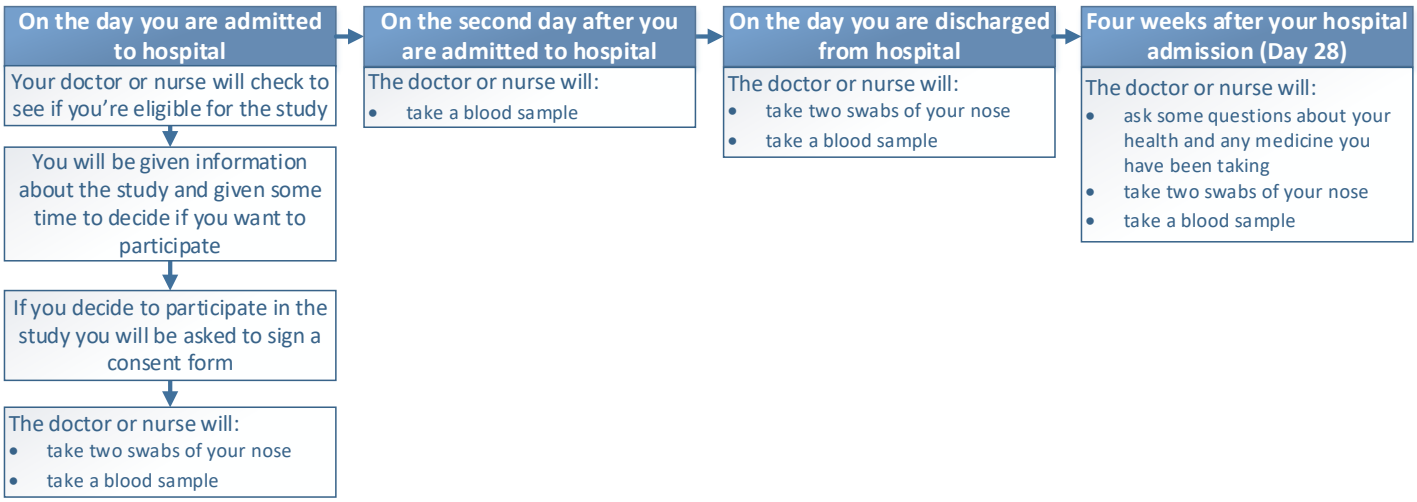
your head back and the doctor or nurse will gently insert a small swab into your nostril and continue to the back of your nose. This might make you gag a little bit or make your eyes water. This procedure will then be repeated in your other nostril. It will take about 3-5 minutes for the doctor or nurse to collect both nose swabs.

Two additional nose swabs will be collected on the day of your hospital discharge.

We will also need specific blood samples taken for the research analysis at three time points during your hospital stay: on admission, on the second day after you are admitted to hospital and on the day you are discharged from hospital. If you are in hospital for less than three days then we will only collect two extra blood samples: on the day you are admitted and on the day you are discharged. 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 your routine hospital care.

About four weeks (28 days) after the date of your hospital admission there will be a final study follow up visit. We may send you a letter or give you a telephone call to remind you of the date and location of your day 28 visit. We will either ask you to return to the hospital, visit your GP or a nurse may visit you at home or at work. During this visit you will be asked some questions about your health and the doctor or nurse will collect two more swabs from the back of your nose and a blood sample.

MERMAIDS-ARI Study procedures



Will my taking part in the study be kept confidential?

Yes. If you join the study, some parts of your 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. Your study data will be de-identified and none of your personal identifiable information will be exported outside of the United Kingdom. The local

research team in [insert site] will be collecting your personal contact details only in order to arrange the follow-up visits for the study. They will keep your personal information confidential and will not pass this on to the University of Oxford. This contact information will be destroyed within three months after the study has ended. 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 you and your 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 you. In the case of research, this is 'a task in the public interest.'

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. Further information about your rights with respect to your personal data is available at

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

You can find out more about how we use your 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 you or your 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 your 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 your doctor was not able to determine the cause of your infection we will still keep and test your samples. We may also use the blood sample to analyse your DNA. We may compare your 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 in a de-identified manner and the results cannot be linked back to you.

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. You will not be told about further tests done to the samples.

Are there any benefits to taking part in this study?

There is no direct personal benefit to you. 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. You may experience some discomfort when the nose samples are collected. During the blood taking you might feel some slight pain and light-headedness and there might be a risk of local bruising from the needle stick.

Where DNA testing is done, your sample and any information recorded about you in this study will be 'de-identified' and assigned a study code as described above. However, your DNA is unique to you so it can never be completely anonymous.

Expenses and Payments

You will receive a £50 gift card to compensate you for the time you have invested in attending all of the study visits. You 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 if I don't want to carry on with the study?

You can withdraw from the study at any time without giving a reason. Withdrawing from the study will not affect your future medical care. If you wish to withdraw from the study please contact the study team using the contact details on the last page. The research team will use the data and samples collected up to your withdrawal, unless you tell us at the time that you withdraw, that you would prefer us not to. If you do not want us to keep your samples and data they will be destroyed.

What happens once the study has stopped?

Once you have 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 you are 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. Your details 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

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