MEDIEVAL ANTIBIOTIC STUDY

Participant Information Sheet

VERSION 1.2

Study Investigators
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Introduction

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish. Please 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.

Who is organising and funding the study?

The study is being co-ordinated by the University of Warwick, and is being led by Dr Freya Harrison (microbiologist) and Professor Julie Bruce (clinical trials). The study is funded by Diabetes UK.

What is the study about?

Bacteria can cause infections. Usually infections are treated with a short course of antibiotics. But, many bacteria have now developed 'resistance' to antibiotics. This means some infections are very difficult to treat. For some people, the infection does not clear up at all. This is a problem for the NHS and for society as some bacteria are now resistant to the most powerful antibiotics. We need to find new ways of treating infections.

Can we learn from the past?

Historians have found very old recipes for treating infections from textbooks written in the Middle Ages. These have been translated and scientists have tried making these recipes in the modern laboratory using up-to-date methods.

What was found?

Scientists from the University of Warwick found that one of the medieval recipe mixtures could kill bacteria under laboratory controlled conditions. The liquid recipe was a mix of leeks, onions, garlic, wine, bile salts – all food stuffs that we can safely eat. These ingredients have been in different combinations (recipes) in the laboratory and they have been found to kill bacteria. Please note that the bile salts used come from cows: the recipe is not vegan.

What does this research involve?

We would like to now test this liquid on some volunteers. We want to see if it is safe to apply the liquid to healthy human skin. This is very similar to a patch test done to test for allergies. This will be done before we can test the liquid on people with infections.

What would taking part involve for me?

We want to recruit a sample of about 90 to 100 volunteers who are willing to have a small sample of the liquid on their skin. We will apply a one to two drops onto a plaster then apply this to your upper arm. We ask you to keep the plaster on, if possible, for **two days.**

What happens next?

After two days, we will ask you to remove the plaster and let us know if there is any skin irritation. We will contact you by phone, email or by video-link (whichever is easiest for you), to ask you some questions. This should take about 10 minutes. If you have skin irritation, we will ask for a digital photograph of the skin area on your arm, with your permission (a mobile phone photo will be adequate). This is so we can store an image of the reaction to the liquid. We will ask your consent for this.

Who can take part?

We are inviting anyone aged from **18 to 79** years to take part. We want to see if the liquid causes any reaction on the skin. If you are pregnant, have diabetes, asthma, sensitive skin, eczema, psoriasis, or are allergic to plasters or garlic (or other foodstuffs), or have broken skin on your upper arms, then you should not take part. We also ask you not to take part if you have any symptoms of COVID-19, or are self-isolating due to COVID-19 exposure, at the time of the study. Finally, we ask that you wear a face covering during your visit to us.

Do I have to take part?

No. You are a volunteer. Participation in this study is completely voluntary and choosing not to take part will not affect you in any way. It is entirely up to you to decide if you want to take part. You can also choose to withdraw your participation at any time, without giving a reason, by contacting a member of

the research team. Further details about withdrawing from the study are provided later on in this document.

What are the possible benefits of taking part?

There is no direct benefit to you from taking part. The findings of this study will help us develop and progress this research. We hope that there may be a benefit in the future for people with infections.

What are the possible disadvantages, side effects or risks, of taking part in this study?

We do not expect any major risks from taking part. A disadvantage is the time you will spend doing the study. There may be some risk of slight skin irritation from the liquid. There may be a slight smell of garlic too. We will ask you to record any symptoms and will ask you about these when we contact you after 2 days. We also ask you come to a clinic at the Warwick Medical School for the liquid to be applied. This clinic will adhere to Covid-19 requirements to protect you and the researchers (wear a mask, only one person at a time at clinic).

What will I be asked to do if I take part in the study?

If you agree to take part after reading this information leaflet and have had your questions answered, you will be asked to sign a consent form and return this to the study team. This consent form asks for permission to take a photograph of the area of skin where the liquid is applied. We would ask you to attend a clinic at the Warwick Medical School to have the liquid applied. This should take 10-15 minutes. Rather than come back to clinic, we will contact you after 48 hours by phone, email or video-link (as you prefer), to ask you some questions.

If you experience any discomfort that makes you want to stop the test, remove the plaster and gently wash the area with soap and water. Please contact us to let us know you have done this. If symptoms persist, we advise you to visit your GP.

Why are you testing the liquid on healthy people?

This is the first stage of the research. This is a clinical trial to test for safety of the product. Then, in the future, we hope to test this liquid on a sample of patients with infections. We would like to test it on people with diabetes who have infected leg ulcers - because of the type of bacteria that infect these wounds.

Expenses and payments

We cannot refund your travel and reimburse you for taking part in the study.

Who will know that I am taking part?

The only people who will know that you are taking part will be the members of the study team. You are free to discuss with anyone else if you wish.

Will my taking part be kept confidential?

We will collect and store information for the study, including your name, gender, age, telephone number and email address. This will be stored on paper and transferred to computer with restricted password-protected access. Paper copies will then be destroyed. Only two members of the study team will have access to this information. If you consent to having an image taken, this will be stored on computer with an ID number allocated to your image. You will not be identified from this image. If you have a tattoo which appears on the image, this image will be destroyed.

How will my data be stored?

All paper records will be stored in a locked cabinet in a locked office and only members of the study team will have access. All information will be stored on a secure server and protected by a password that is known only to the study team. All information that is collected during the study will be kept confidential at all times and in compliance with the General Data Protection Regulations. No personal data will be shared or transfer to other organisations outside of the University. We may use photographic images for scientific report or publications, but only if you consent for these to be used.

What will happen to the data collected about me?

As a publicly-funded organisation, the University of Warwick have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study such as this, we will only use your data in the ways needed to conduct and analyse the research study.

We will be using information from you in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The University of Warwick will not keep identifiable information about you after the study has finished. Research data will be **anonymised** (by removing your name) as quickly as possible after data collection and it will not be possible to withdraw your data after this point.

Data Sharing

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. The University of Warwick has in place policies and procedures to keep your data safe. These data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

For further information, please refer to the University of Warwick Research Privacy Notice which is available here: https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?

Your participation is entirely voluntary, and you can withdraw at any time without giving a reason. You may ask to withdraw verbally on the day you visit us to have the plaster applied, or afterwards by contacting a member of the study team using the contact information at the end of the leaflet.

Please note that withdrawing your participation is separate to withdrawing data that has already been collected during the study. If you withdraw from the study and your data has already been anonymised, it will not be possible to withdraw your data which has already been collected. We will wait at least two weeks after the last participant has had their follow-up visit before anonymising study data. To safeguard your rights, we will use the minimum personally-identifiable information possible and keep the data secure in line with the University's Information and Data Compliance policies.

Who has reviewed the study?

This study has been approved by Diabetes UK. It has been given favourable opinion by the University's Biomedical and Scientific Research Ethics Committee (BSREC): XX/XX.

What will you do with the findings of the study?

The findings of the study will be reported anonymously to Diabetes UK and published in medical journals and on social media (Twitter). We will also present the findings to scientists, doctors and other health social care professionals. We will email a summary of study findings to any participant who would like this.

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Research & Impact Services, University House, University of Warwick, Coventry, CV4 8UW.

Email: researchgovernance@warwick.ac.uk Tel: 024 76 522746

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer, who will investigate the matter: DPO@warwick.ac.uk If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Who should I contact if I want further information?

If you have any questions about the study, do please contact the study team by email, telephone or in writing to:-

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Thank you for taking the time to read this Participant Information Leaflet