University of Hertfordshire UH

PARTICIPANT INFORMATION SHEET

Title of study: Hair and skin decontamination trial to investigate the effect of individual and combined actions upon the distribution of simulant contamination in human volunteers

Introduction

You are being invited to take part in a study. Before you decide to do so, it is important that you understand the research that is being done and what your involvement will include. Please take the time to read the following information carefully and discuss it with others if you wish. Do not hesitate to ask us anything that is not clear or for any further information you would like to help you make your decision. Please take your 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?

This research study is part of a project which will examine procedures that the US emergency services use to clean (decontaminate) large numbers of people who have potentially been contaminated during an incident in which chemicals have been released. This study, conducted by the University of Hertfordshire (hereafter referred to as UH), UK will investigate how a non-toxic chemical simulant spreads on hair and skin after showering using the Ladder Pipe System and a towel or a dry decontamination method either alone or in combination with the standard technical decontamination shower procedure.

Where and when will the study take place?

The study will take place at the UH facility in Ludgershall, Wiltshire. A member of the University's trial staff will discuss your participation with you, including the specific instructions involved. If you decide to participate we will send you a confirmation email containing this information and directions to the site.

What do I do if I am interested?

If you would like to take part, please carefully read the rest of this information sheet and the medical eligibility criteria, ensuring you are able to participate. Then please contact research-trials@herts.ac.uk to book. Additionally, if you would like further information or have any concerns, please contact the research team on the details below.

Please note, you are under no obligation to take part and you are free to withdraw from the study at any time. This will not affect the care and supervision that you will receive.

Who should I contact for more information / to sign up?

Please contact our project team. We would be very happy to discuss this further, answer any questions you may have and, if you wish, arrange for you to participate in this project.

Email: research-trials@herts.ac.uk

If you have a concern about any aspect of this study, you should ask to speak to the researchers via the email above, who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through contacting the University's Secretary and Registrar on 01707 284080.

Further Information

How do we assess the presence of the chemical simulant on the skin and hair?

Everybody who participates in the study will undergo the same procedures. Researchers will be available to assist you and answer any questions you may have.

We will spray a small quantity (2 g) of a liquid mixture of two foodstuffs from a fixed distance above you, onto your hair and skin using a low pressure spray gun. The spray will be in two short bursts (1-2 sec each). No more than a total of 1 g of the mixture will come into direct contact with you. After 4, 8 or 12 minutes, we will ask you to decontaminate using either a dry decontamination method, Ladder Pipe System, or showering tent or a mixture of up to all three.

One of the substances is a fluorescent foodstuff called curcumin. We will check how much has been on the hair and skin by photographing you under an ultraviolet light. The amount of ultraviolet light to which you will be exposed is very low (around 20 times lower than you would be exposed to on a winter's day). In rare cases, some individuals have a pre-existing food allergy to curcumin (turmeric) and we would ask that you disclose this if known before participating in this study.

The other substance, methyl salicylate, is a food and cosmetic flavouring and an active ingredient in topical 'muscle creams' such as Deep Heat™. It has been used for the last 50 years to train emergency responders and military personnel in the art of decontamination. The pain relief of these creams and sprays is due to the methyl salicylate being converted into an aspirin-like compound. In this study, your exposure to methyl salicylate is equivalent to less than two aspirin tablets. If you think you may be allergic to aspirin, have another medical condition that prevents you taking aspirin, or are taking another drug that does not "mix" with aspirin you should not participate in this study.

Eighteen minutes after decontamination, we will measure how much methyl salicylate is present on your hair and scalp by applying cotton wool swabs containing alcohol to the area of your head where the mixture was sprayed. Similarly, after decontamination we will measure how much methyl salicylate is present on your skin by taking skin swabs to a number of sites on your body.

What will happen during the study?

If you would like to participate in the trial, please contact the University to speak with a member of the University's trial staff. We will then send you further information including a brief health screen questionnaire. Please return the completed questionnaire to us for review. If you are eligible to participate, a member of the trial staff will then contact you to arrange for you to attend our facility located in Ludgershall.

If you are eligible, you will be sent additional important information leading up to the beginning of the trial. **Please read this additional information carefully as it may affect your eligibility to participate in the trial**. For example, you will be reminded that you cannot participate if you take aspirin or products containing aspirin (e.g. Anadin™) in the 24 hours prior to the study. On the days of the study, you will be provided with full instruction and researchers will be available to answer any questions you may have.

On the agreed day, you will have the opportunity to reread this Participant Information Sheet and ask any further questions. It is completely up to you whether or not you decide to take part in this study. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.

After enrolment, you will asked to change into swimwear and a set of 5 full body photographs will be taken under UV lights. You will not be identifiable in these images. These are baseline photographs to demonstrate that there is nothing fluorescent on your body that would influence the measurement of the simulant. You will also be asked to provide a baseline urine sample as we will be looking for the presence of methyl salicylate in your diet. NB Your modesty is very important to us so female participants will be chaperoned and assisted only by female trial staff and all subsequent study activities whilst disrobed will be performed behind screens. Male volunteers will be similarly chaperoned and assisted by male trial staff.

You will then be provided with a nose clip and disposable mouthpiece fitted to a breathing tube to minimise inhalation of the simulant and goggles to protect your eyes during dosing. We will ask you to enter the exposure room where a trained member of UH staff will apply a short spray of the simulant mixture from above you. You will notice that methyl salicylate has a distinctive smell (Oil of Wintergreen).

After the application of the simulant, you will be asked to have a second set of 5 full body photographs under UV light. You will not be identifiable in these images.

You will then be asked to wait 4, 8 or 12 minutes before undergoing one or more of three decontamination interventions. After each intervention, we will acquire a set of photographs (max = 3 sets) under UV light You will then be asked to decontaminate using either 1) a dry decontaminant material or 2) via use of the Ladder Pipe System (LPS) which involves walking though a corridor for a 15 second shower of large volume, low pressure unheated water followed potentially by active drying with a towel. The third possible decontamination procedure is via a showering tent in which you will stand for a 90 second shower of large volume, low pressure warm soapy water followed potentially by active drying with a towel. The dry decontaminant and towels will be collected and later analysed for the presence of methyl salicylate.

Eighteen minutes after dosing a number of skin sites will also be swabbed with cotton wool. The top of your head (scalp and hair) will also be swabbed with cotton wool. You will then be asked to have a final set of full body photos taken. You will not be identifiable in any of these UV images and after the final images you will be able change back into your normal clothes.

Agreeing to join the study does not mean that you have to complete it. You are free to withdraw at any stage without giving a reason. A decision to withdraw at any time, or a decision not to take part at all, will not affect any treatment/care that you may receive.

What happens after the study?

To avoid influencing the measurement of salicylate in your urine, we will ask you not to apply any products containing methyl salicylate (e.g. Deep Heat™) to your body for 24 hours before and after the study day or to take any aspirin-containing medicines.

At the end of the study day, you will be provided with a set of instructions, a sealable box and a 5L container in which to collect your urine for the next 24 hours. You will also be asked to return the urine the following day whereupon you will be fully debriefed by a member of the research team who will outline the aims of the study and also the volunteers' contribution to those aims.

Additionally, you will be given an information sheet to take away with them. This will contain contact information of the research team so you can contact the team with any questions or to discuss any issues that arise after completion of the trial.

Is there any risk?

The study involves well-practiced procedures carried out by fully trained UH research staff.

It is important that you read the accompanying medical eligibility criteria as you may not be able to participate if you have some existing health conditions. If you are interested, but are unsure whether you are eligible, please contact us on the details provided above.

What safety precautions are in place for this study?

All procedures employed have been scrutinised by the University of Hertfordshire ethics committee and have been subjected to comprehensive risk assessments. All members of staff are fully trained and will follow comprehensive Standard Operating Procedures.

UH staff members will be on hand at all times to help you if you have any questions or concerns.

How will my information be stored / used in the future?

The data you provide during this study will be kept confidential and anonymous in accordance with the 1998 UK Data Protection Act. At no point will any data be associated with your name or identity.

Your data will be retained for 20 years after the study. At no point will you be identified. Your data will be held confidentially, with access restricted to researchers working in the University of Hertfordshire. Once your data has been analysed, it may be used in publications in academic journals and reports. It may be presented to a variety of academic and professional audiences but you will not be identified.

Once the data has been analysed, it will not be possible to withdraw, however, if you wish to have your data deleted prior to analysis for any reason, please contact the researchers and, wherever possible, your request will be obliged.

Will your place in the study be guaranteed?

Once you have completed your consent form and your eligibility has been confirmed you will be enrolled onto the study. On the day itself, we will require you to confirm that there have been no changes to your medical status. If necessary, we may ask you to be interviewed by a medical staff member. It is possible that you may not meet the eligibility criteria at this point and you will be excluded from the study, but you will still be reimbursed for your time. If you have carefully read the medical screen and followed the instructions it is unlikely that you would be excluded at this stage. If however, you are unable to take part this time we hope that you would consider taking part in similar studies or exercises that will be held in future.

Who is carrying out this study?

This study is being carried out by the University of Hertfordshire, UK.

Who has reviewed this research study?

All human volunteer research performed by the University of Hertfordshire is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study (Protocol acLMS/SF/UH/02476(2) has been reviewed and given favourable opinion by the University of Hertfordshire Ethics Committee.

Thank you for reading this information and giving consideration to taking part in this study.