ISRCTN61073828 https://doi.org/10.1186/ISRCTN61073828

Evaluation of a clinical decontamination protocol

Submission date	Recruitment status
23/08/2017	No longer recruiting
Registration date	**Overall study status**
24/08/2017	Completed
Last Edited	**Condition category**
24/05/2018	Injury, Occupational Diseases, Poisoning

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The accidental or deliberate release of a hazardous substance may result in a large number of contaminated casualties. The rapid cleaning of exposed skin and hair surfaces (decontamination) is critical to ensuring the wellbeing of all casualties. During an incident, some casualties may need to undergo a specialised form of decontamination known as non-ambulant clinical decontamination. This process takes place in clinical decontamination units which provide a sheltered area for injured (non-ambulant) casualties to be showered with warm water by ambulance personnel wearing full personal protective equipment known as PRPS (powered respirator protective suit). The current process for clinical decontamination is poorly defined, is difficult to perform when wearing PRPS and can take up to 15 minutes per person. Recent studies have identified a new clinical decontamination process. The new method is shorter (5 minutes) and can be performed by staff wearing PRPS. However, the effectiveness of the new process has not been tested. Therefore, the aim of this study is to assess the effectiveness of the new clinical decontamination response using human volunteers.

Who can participate?
Volunteers aged 18 – 60

What does the study involve?
Each participant is asked to wear a swim suit. Exposed skin/hair surfaces are “dosed” at various sites with a liquid chemical mixture which has a safe history of use in previous studies. The participants are then randomly allocated to either be treated using the new clinical decontamination protocol or to receive no treatment. The amount of chemical remaining on the hair and skin surfaces is measured and compared between the two groups.

What are the possible benefits and risks of participating?
There is no immediate benefit to the participants. It is not anticipated that there will be any side effects as a result of participation in this study.

Where is the study run from?
Intertox Ltd (UK)

When is the study starting and how long is it expected to run for?
February 2017 to March 2017

Who is funding the study?
Zeal Solutions Ltd (UK)

Who is the main contact?
Tracey Thomas

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
ITX-IERC-0217A

Study information

Scientific Title
Evaluation of a non-ambulant clinical decontamination procedure

Study objectives
Clinical decontamination has no significant effect on reducing dermal exposure to a liquid chemical in non-ambulant, contaminated casualties.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Ethical Review Committee, 03/03/2017, ref: ITX-IERC-0217A

Primary study design
Interventional

Study design
Randomised blind control design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Exposure to toxic materials

Interventions
Volunteers were randomly assigned to each treatment group using an online treatment allocation generator (Urbaniak, G. C., & Plous, S. (2013). Research Randomizer (Version 4.0) [Computer software]. Retrieved on 22/06/2013, from http://www.randomizer.org/). One group will be subject to the revised clinical decontamination protocol following exposure to a curcumin /methyl salicylate mixture (CMX). The second group will be exposed to CMX but will receive no other intervention.

Each participant will be asked to wear a swim suit. Exposed skin/hair surfaces will be “dosed” at various sites with a liquid chemical mixture which has a safe history of use in previous studies. The participants will then be treated using the revised clinical decontamination protocol or receive no other intervention according to which group they are allocated to. The amounts of chemical remaining on the hair and skin surfaces will subsequently be quantified and compared to a group of participants who have not been treated.

Fluorescent images of each participant will be acquired (i) before exposure (baseline), (ii) following contamination and (iii) on completion the study session. Swabs of the exposed skin and hair surfaces will be taken at the end of the study session. The fluorescent images will be subject to a validated image analysis protocol to determine the distribution of the contaminant. The swabs will be analysed by LC-DAD-MS (liquid chromatography – diode array detector – mass spectrometry) to quantify the amounts of CMX recovered. The primary outcome will be a comparison of the average amounts of chemical contaminant recovered from the skin and hair surfaces of participants between the two treatment groups. Secondary outcomes will be to determine any differences in the surface distribution (fluorescent images) between the two treatment groups.

The chemical contaminant used in the study will be a mixture of a fluorescent compound (curcumin; 10 mg mL-1) dissolved in methyl salicylate (‘CMX’). This will be applied to each volunteer as a 10 µL droplet (hair and skin surfaces) or as a 100 µL droplet (over clothing). The total dose of methyl salicylate will not exceed 720 µL (equivalent to 0.84 g of aspirin).

Intervention Type
Other

Primary outcome(s)
The effectiveness of the protocol, determined by LC-DAD-MS measurements of the amount of a chemical contaminant (curcumin/methyl salicylate mixture) recovered from the hair and skin of exposed participants in comparison with a control (exposed, untreated) treatment group

Key secondary outcome(s)
Semi-quantitative determination of the area of contamination on hair and skin surfaces, observed by fluorescent imaging of exposed participants in comparison with a control (exposed, untreated) treatment group

Completion date

24/03/2017

Eligibility

Key inclusion criteria
1. Volunteers
2. Male or female
3. Age 18 – 60 (at the start of the study)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Allergy to aspirin
2. Currently taking blood-thinning agents (anti-coagulant or anti-platelet)
3. Renal impairment
4. Inflammatory disorder affecting the skin
5. Partially healed/open wounds
6. Respiratory condition (other than controlled asthma)
7. Pregnant or breastfeeding
8. Any other relevant condition at the discretion of an independent physician

Date of first enrolment
03/03/2017

Date of final enrolment
07/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Intertox Ltd
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Sponsor information

Organisation
Intertox Ltd

Funder(s)

Funder type
Industry

Funder Name
Zeal Solutions Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to issues of data confidentiality.

IPD sharing plan summary
Not expected to be made available