ISRCTN12832762 https://doi.org/10.1186/ISRCTN12832762

Evaluation of emergency dry decontamination

Submission date
23/08/2017

Recruitment status
No longer recruiting

Registration date
24/08/2017

Overall study status
Completed

Last Edited
24/05/2018

Condition category
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 removal of clothing (disrobe) and cleaning of exposed skin and hair surfaces (decontamination) is critical to ensuring the wellbeing of all casualties. However, there is currently no formal process for treating casualties who are unable to perform disrobe and decontamination on themselves. Such casualties are categorised by the general term non-ambulant. Therefore, the aim of this study is to develop a new procedure that will allow ambulance staff to perform effective disrobe and decontamination on behalf of non-casualties. Previous studies have demonstrated that for most liquid chemicals, decontamination is best performed using dry, absorbent materials. In an emergency, an Ambulance Crew would need to use any readily available material such as wound dressings, incontinence pads or 'blue roll'. Blue roll is a type of paper towel which is available on all ambulances and so is an ideal candidate for use as a decontamination product. The aim of this study is to assess the effectiveness of disrobe and decontamination (using blue roll) using human volunteers.

Who can participate?
Volunteers aged 18 – 60

What does the study involve?
Each participant is given a set of over-clothes to wear and a swim suit to wear underneath the clothes to preserve modesty. The clothes and exposed skin/hair surfaces are "dosed" at various sites with a liquid chemical which has a safe history of use in previous studies. Participants are randomly allocated to one of two groups. Participants in one group are disrobed by cutting away their clothing using a standard Ambulance Service method and decontaminated using blue roll. Participants in the other group are not treated. The amount of chemical remaining on their hair and skin is measured and compared between the two groups.

What are the possible benefits and risks of participating?
There is no immediate benefit to volunteers. 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
Mrs Tracey Thomas

Contact details
Unit 5C
Brydges Court
Ludgershall
Wiltshire
Andover
United Kingdom
SP11 9FT

Additional identifiers

Protocol serial number
ITX-IERC-0117A

Study information

Scientific Title
Development of a non-ambulant dry decontamination procedure: a randomised controlled trial

Study objectives
The null hypothesis is that disrobe and dry 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 Ethics Review Committee, 24/02/2017, ref: ITX-IERC-0117A

Study design
Randomised blind control design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Contamination with toxic material

Interventions
All participants will be dosed with a fluorescent chemical contaminant over a total of 16 discrete areas of clothing, hair and skin. They are randomly assigned to two groups 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/). Individuals in one group will then undergo disrobe and decontamination, with the other group being untreated (control). Eight individuals will be allocated to each treatment group. The purpose of the study will be to quantify the relative effectiveness of disrobe and decontamination in removing the contaminant by comparison with no treatment (controls).

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))
The distribution of the chemical mixture on hair and skin surfaces, observed by fluorescent imaging of exposed participants in comparison with a control (exposed, untreated) treatment group

Completion date
20/03/2017

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. Renal impairment
3. Inflammatory disorder affecting the skin
4. Partially healed/open wounds
5. Respiratory condition (other than controlled asthma)
6. Pregnant or breastfeeding
7. Any other relevant condition at the discretion of an independent physician

Date of first enrolment
27/02/2017

Date of final enrolment
06/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Intertox Ltd
United Kingdom
SP11 9FT

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 data confidentiality issues.

IPD sharing plan summary
Not expected to be made available