

Evaluation of emergency dry decontamination

Submission date 23/08/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/05/2018	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Randomised blind control design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

27/02/2017

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

18

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

England

United Kingdom

Study participating centre

Intertox Ltd

United Kingdom

SP11 9FT

Sponsor information

Organisation

Intertox Ltd

Sponsor details

5C Brydges Court

Ludgershall

United Kingdom

SP11 9FT

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Zeal Solutions Ltd

Results and Publications

Publication and dissemination plan

The study protocol is available on request. It is intended to publish the result of this study in a relevant, peer-reviewed journal within 24 months of completion of the study.

Intention to publish date

24/06/2018

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