

# Randomised controlled clinical trial to test the effectiveness of reusable burn gloves vs polythene bags as hand burn treatment

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/12/2019	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
RRCC27R HALL M

## Study information

**Scientific Title**

Randomised controlled clinical trial to test the effectiveness of reusable burn gloves vs polythene bags as hand burn treatment

### **Study objectives**

Will the clinical effectiveness of this new re-usable burn glove, made with a bacterial barrier, water vapour permeable fabric, be an improvement on the current treatment of polythene bags for partial thickness hand burns? Will the new treatment be cost effective? Partial thickness and superficial hand burns are treated mostly as outpatients. They need frequent redressing until healed, and are therefore costly to the NHS. Treatment of hand burns by bandaging methods in children and by polythene bags in adults, is debilitating, greatly reducing the patients ability to carry out the activities of daily living. Frequent dressing changes are necessary because of the moisture leaked from the burn. In the polythene bag treatment, the skin becomes macerated (soggy), as the bag fills with fluid. The accumulation of fluid in the bag reduces function of the hand during treatment. The semi-permeable and bacterial barrier nature of the fabric glove allows evaporation of the fluid, reducing the maceration, but keeping the burn moist and clean. The gloves are machine washable between use on the same patient and need washing and then sterilising before use on a new patient. The number of times the glove is washed will be recorded. The gloves will be laboratory tested by Lojigma for their effectiveness at the end of the trial.

The randomised controlled clinical trial will test the clinical effectiveness in terms of healing time, infection rates, maceration, comfort, pain and function of the hand during treatment. Nurses in the recruiting Accident and Emergency and Minor Injuries Departments will be trained to carry out the trial.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Not Specified

### **Health condition(s) or problem(s) studied**

Injury, occupational diseases, poisoning: Burns

### **Interventions**

1. Reusable hand gloves
2. Polythene bags

### **Intervention Type**

Other

### **Phase**

Not Applicable

**Primary outcome(s)**

1. Healing time - measured in days from burn to healed
2. Infection rates - clinical infection treated with antibiotics
3. Bacterial barrier properties of materials - wound swabs to be taken
4. Maceration - clinical judgement made by nurses - confirmed with photographs
5. Comfort and ability to carry out activities of daily living - patient questionnaire
6. Pain - patient questionnaire
7. Movement of hand - measurements made by nurses
8. Assessing the life of the gloves - record number of washes
9. Gloves effectiveness to be tested by Lojigma at end of trial

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

07/01/2000

**Eligibility****Key inclusion criteria**

1. Patients who agree to enter the trial, aged 16 plus who present within 48 hours of the burn in York, Harrogate or Northallerton A&E Departments or Selby Minor Injuries Department
2. They should have with partial thickness hand burns of at least 10% of the hand

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

05/01/1999

**Date of final enrolment**

07/01/2000

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**  
York Health Services NHS Trust  
Selby  
United Kingdom  
YO8 9BX

## **Sponsor information**

**Organisation**  
NHS R&D Regional Programme Register - Department of Health (UK)

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
NHS Executive Northern and Yorkshire (UK)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration