

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

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/12/2019	Condition category 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

Contact name

Mrs Marion Hall

Contact details

York Health Services NHS Trust
Minor Injuries Dept, Selby War Memorial Hospital
Doncaster Road
Selby
United Kingdom
YO8 9BX
+44 (0)1757 701 314
a@b.c

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

05/01/1999

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

Age group

Adult

Sex

Both

Target number of participants

Not provided at time of registration

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**

England

United Kingdom

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)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)**Funder type**

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration