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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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
12/12/2019

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
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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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