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Acceptability and effectiveness of Burnshield dressing in the early treatment of uncomplicated partial thickness burns in the A&E Department

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/10/2011	Injury, Occupational Diseases, Poisoning	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0226187455

Study information

Scientific Title

Study objectives
To investigate the effectiveness of a Burnshield dressing as first treatment in patients with uncomplicated partial thickness burns in reducing infection and pain as compared with standard treatment.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Burns

Interventions
1. Burnshield
2. Atrauman (standard treatment) for 24 hours

After 24 hours all patients will receive Atrauman dressing.

Added September 2008: trial was stopped due to lack of resources.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pain scoring (Wong and Baker scale) and analgesia usage between Burnshield and Atrauman groups.

Secondary outcome measures
No secondary outcome measures

Overall study start date
03/01/2007

Completion date
03/08/2007

Reason abandoned (if study stopped)
Lack of resources

Eligibility

Key inclusion criteria
1. Age over 1 year
2. Partial thickness burn under 10% of body surface area
3. Injury less than 2 hours old
4. Patient/parent consents

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Sex
Not Specified

Target number of participants
242 participants; 121 (50%) in control group

Key exclusion criteria
1. Age <1 year
2. Pregnancy
3. First aid other than cold water, soaked dressings or cling film
4. Requiring fluid resuscitation or referral to plastics
5. Requiring admission for other injury
6. Systemic disease likely to affect healing (DM, PVD)

Date of first enrolment
03/01/2007

Date of final enrolment
03/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital of South Manchester NHS Foundation Trust
Manchester
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M23 9LT

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital of South Manchester NHS Foundation Trust (UK), NHS R&D Support Funding

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