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

Submission date 28/09/2007	Recruitment status Stopped	Prospectively registered
		☐ Protocol
Registration date 28/09/2007	Overall study status Stopped	Statistical analysis plan
		☐ 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

Contact name

Mr Nick Payne

Contact details

University Hospital of South Manchester NHS Foundation Trust Wythenshawe Hospital Southmoor Road Manchester United Kingdom M23 9LT +44 0161 291 6048 nick.payne@uhsm.nhs.uk

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 United Kingdom 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 London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration