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Randomised controlled trial of excision and grafting with same flap, deffating of skin flap and treatment with steristrips of pre-tibial skin lacerations

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/04/2015	**Condition category** Surgery	[_] Individual participant data [_] 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

N0224149878

Study information

Scientific Title
Randomised controlled trial of excision and grafting with same flap, deffating of skin flap and treatment with steristrips of pre-tibial skin lacerations

Study objectives
What is the best treatment option in an A and E setting for cases of pre-tibial lacerations? Three different treatments will be compared to try to establish the better option for patients attending A and E. Healing times will be specifically looked at in each category and pain scores to help improve patient care for the future.

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
Surgery: Skin transplantations

Interventions
Excision and grafting with the same flap versus deffating of the skin flap versus put ting steristrips to hold the skin.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Is there any reduction in mean healing time with any suggested treatments?
Any improvement in pain scores?

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/06/2004

Completion date
30/04/2007

Eligibility

Key inclusion criteria
Patients attending A and E with pre-tibial lacerations.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Number of patients to recruit = 200

Key exclusion criteria
1. Patients who are unable to decide for themselves, patients with dementia, mentally ill
2. Those who cannot understand English/need an interpreter
3. Patients on anticoagulants except aspirin

Date of first enrolment
24/06/2004

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Devon Health Care NHS Trust
Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
South Devon Healthcare NHS 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