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

Recruitment status	 Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Surgery	Record updated in last year
	No longer recruiting Overall study status Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Graham Gardner

Contact details

South Devon Health Care NHS Trust Torbay Hospital Lawes Bridge Torquay United Kingdom TQ2 7AA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 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

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 summaryNot provided at time of registration