ISRCTN80435760 https://doi.org/10.1186/ISRCTN80435760

The effect of local anaesthetic on skin graft thickness and cell culture

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/08/2009	Surgery	

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
N0265166240

Study information

Scientific Title

Study objectives
1. We want to revisit the anatomy of a split skin graft. Our understanding of the healing of donor sites is based on work done in the 1920s at a time when grafts were taken by a hand knife. We are not sure the modern mechanical dermatomes take the same amount of skin or damage the same amount of the dermis (the deeper layer of skin that is left behind when a graft is taken). Therefore we wish to look at the skin that is left behind histologically following the harvest of split skin using a mechanical dermatome set at various thicknesses.
2. We wish to look at the effect of EMLA (eutectic mixture of local anaesthetics) on the skin thickness that is left behind for the same dermatome settings.
3. We also want to know if local anaesthetics interfere with cell growth which is of great importance when harvesting skin for culture in burns patients.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Skin graft

Interventions
EMLA cream is frequently used in the harvesting of split skin grafts. It provides sufficient anaesthesia for grafts to be taken without any supplemental anaesthetic agent. Reports suggest the application of EMLA cream may result in variations in skin thickness. This change in skin thickness may have significant consequences on the subsequent graft taken. The aim of this study is to assess histologically the effect of EMLA cream on the thickness of split skin grafts taken and the effects of local anaesthetics on skin culture.

Methods
A randomised controlled trial will be performed to assess the thickness of split skin grafts taken using EMLA cream and the effect of local anaesthetic on cell culture. The investigators, who will

provide verbal and written information regarding the trial, will approach patients. If the patient agrees to participate written consent will be obtained.

Materials
EMLA cream, occlusive dressings, lidocaine

Preoperative Preparation
The operating surgeon will mark the abdomen for the abdominoplasty procedure. The surgeon, will then offer the patient envelopes in order to randomise EMLA to either the right or left side of the abdominoplasty. The cream will then be applied and an occlusive dressing applied at least 2 hours prior to surgery.

Intraoperative Procedure
In theatre, the occlusive dressing and cream will removed from the abdomen. Lignocaine will be injected under the skin on the other side of the abdomen. The dermatome will be used to harvest the split skin grafts. The dermatome thickness will be adjusted so three grafts of varying thickness will be taken on across the abdomen (4, 8, 12 /1000th of an inch). Six core biopsies (6mm in diameter) will be taken from the edge of the donor sites. These specimens will then placed in formalin to fix
the tissue for analysis be forwarded to the histopathology department for histological analysis. A further three core biopsies from each area will be taken for cell culture. These will be wrapped in saline soaked gauze, and sent in plain sterile containers carefully labelled to the skin laboratory. The abdominoplasty procedure will continue as normal following excision of the unwanted abdominal skin. Postoperatively, the patient will require no further follow-up from the study investigators and no long term consequences from the study are anticipated as the skin used would have been discarded anyway.

Histological Assessment
Core biopsies will be taken from the edges of the donor sites to include adjacent normal skin. This method will allow analysis of the thickness of skin removed. Once this analysis has been performed and results recorded, the specimens will be destroyed. Photographs of histological findings with all patient identifiers removed may be used in the publication of results.

Cell culture Assessment
Using standardised cell culture techniques, the skin biopsies from each area of local anaesthetic and control will be cultured. Cell counts will be performed for keratinocytes and fibroblasts at the appropriate intervals.

Statistical Analysis
The skin thicknesses for the EMLA and control specimens will then be analysed for statistical significance as discussed with the Trust statistician.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
EMLA cream, lidocaine

Primary outcome measure

Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/10/2005

Completion date
14/10/2008

Eligibility

Key inclusion criteria
Patients undergoing abdominoplasty surgery will be recruited for the trial. These patients will be recruited from clinics where they have attended for discussion of the procedure. The area of skin to be discarded as part of the routine abdominoplasty procedure will be used for the trial. If the patient agrees to participate written consent will be obtained. Inclusion criteria include:
1. Low anaesthetic risk patients (ASA I)
2. Previous sensitivity to opsite, EMLA, lidocaine or prilocaine, as these are the materials to be tested.
Long term steroid use, as this affects the structure of the skin (by thinning it), and can affect wound healing, which may adversely affect the cell culture

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Long term steroid use, previous adverse reaction to EMLA, prilocaine or lidocaine.

Date of first enrolment
08/10/2005

Date of final enrolment
14/10/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Burns & Plastics
Birmingham
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
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Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2008		Yes	No