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Can skin grafting success rates in burn patients be improved by using a low friction environment?

Submission date
19/11/2015

Recruitment status
No longer recruiting

Registration date
19/11/2015

Overall study status
Completed

Last Edited
19/12/2018

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In recent years, a lot of progress has been made in the treatment of burns. For particularly severe burns which are very deep, drastic treatment is often needed in which the dead tissue is removed (excision) and healthy skin from elsewhere on the body is transplanted over the top (skin graft). Recovering from this type of procedure is a difficult and painful process. Patients require expert medical care to ensure that their wounds do not become infected or leave disfiguring scars. Unfortunately around 20% of skin grafts do not take properly, which can mean further operations and longer hospital stays. This is both distressing to the patient and expensive to the NHS. Graft loss can be caused by rubbing or stretching the skin, which causes the new graft cells to move around and not attach properly to the wound. A possible reason for this could be because of friction (the resistance of motion) or shearing (when two surfaces move in opposite directions) between dressings and bed sheets. Reduced friction (slippery) bed sheets are in use in the UK with premature babies and other patients to prevent pressure sores, but they are not yet in use in burn units. This study is looking at whether reduced friction bed sheets can help to improve skin grafting success rates in burns patients. The aim of this study is to find out whether enough patients are available and willing to participate in a larger study, whether the required information can be collected from patients and their medical records in order to assess the effects of the bed linen on grafting success rates, and whether staff and patients who use the sheets will be willing to do so in a larger study.

Who can participate?
All burns patients over one month old who need a skin graft, and have been admitted to a participating burns unit for at least one night.

What does the study involve?
All patients who are admitted to one of the participating burns unit for at least one night are looked in beds made up with low friction sheets. The patients are then interviewed in order to find out how comfortable they found the sheets. Over the next 15 months, patients are regularly followed up so that the skin graft success rate can be worked out.

What are the possible benefits and risks of participating?
Potential benefits of participating in this study include possible reduced loss of skin grafts, reduced need for further operations, reduced time in hospital and a need to be readmitted to hospital. The study also offers patients with burns the chance to be involved in a research project intended to benefit patients. Potential risks include the possibility of slips and falls or sores due to pressure or other reasons.

Where is the study run from?
University Hospitals Bristol NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2015 to December 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Susan George

Contact information

Type(s)
Public

Contact name
Ms Susan George

Contact details
University Hospitals Bristol NHS Foundation Trust
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Upper Maudlin Street
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United Kingdom
BS2 8AE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19367

Study information

Scientific Title

Can Skin graftIng success rates in burn patients be improved by using a Low friKtIon Environment – a feasibility study?

Acronym
SILKIE

Study objectives
The aim of this study is to investigate whether the introduction of a novel low friction nursing environment designed to improve skin grafting success in patients with burns is feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 4, 25/06/2015, ref: 15/WA/0156

Study design
Multi-centre non-randomised feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Children, Injuries and emergencies; Subtopic: All Diagnoses, Injuries and Emergencies (all Subtopics); Disease: Injuries and Emergencies, All Diseases

Interventions
All eligible patients in two burn services (three hospital sites) will be cared for using low friction nursing as standard management. This involves low-friction bottom sheets, pillow cases and lined slings depending on body area grafted. This will commence immediately post-operatively through to hospital discharge or wound healing.

Data will be collected prospectively on all patients with burns requiring skin grafts and staying more than one night in hospital. Demographic data, data relating to the burn, graft failure (primary outcome for a full trial), pain, wound infection, length of hospital stay, re-admission and

a need for re-grafting will be collected. This data is compared to data from patients meeting the same inclusion criteria for 12 months prior to study start and prior to the use of low friction bedding.

Qualitative information is collected through interviews with consenting patients, parents, carers and staff. Health economic data is collected through family resource use questionnaires undertaken within 28 days of surgery. Age-appropriate EQ 5D questionnaires are completed pre-operatively and within 28 days after surgery with consenting patients or parents/carers.

Intervention Type
Other

Primary outcome measure
Feasibility of using low-friction bedding in skin grafted, burn injured patients will be determined through interviews with patients and carers at 3 months.

Secondary outcome measures
Clinical outcomes
1. Percentage graft loss as determined by consultant surgical team when graft failure has been confirmed
2. Hospital re-admission rate
3. Diagnosis of wound infection defined as positive swab results and prescription of antibiotics
4. Validation of the iBID grafting and re-grafting rates for use as an outcome in a full trial

Patient reported measures:
1. Pain scores assessed using age-appropriate standardised self-report questionnaire measures including Wong-Baker, FLACC, Modified Objective Pain Score, and Visual Analogue Scale/ Numeric Rating Scale at 12 and 24 hours post-graft for both the donor and graft sites
2. Quality of life assessed using age appropriate EQ-5D questionnaires pre-operatively and within 28 days after injury

Overall study start date
01/05/2014

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Aged between 4 weeks to 100 years
2. Study participant requiring skin grafting of burn injured skin as part of the planned care
3. Nursed on a bed and admitted overnight or longer to one of the three burns services

Participant type(s)
Patient

Age group
Mixed

Sex

Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Key exclusion criteria
1. Patients who are ventilated or on inotropes
2. Patients in whom VAC dressings were used to maintain grafts
3. Patients in whom consent is not possible will be excluded from questionnaire & interviews. In the case of children, parents will consent to participation, with older children giving assent

Date of first enrolment
05/10/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Royal Hospital for Children
University Hospitals Bristol NHS Foundation Trust
Paul O'Gorman Building
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Southmead Hospital
North Bristol NHS Foundation Trust
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Queen Victoria Hospital
Holtye Road

East Grinstead
United Kingdom
RH19 3DZ

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

Sponsor details
Research & Development, Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. The protocol will be submitted for publication before the end of recruitment
2. The final study report will be submitted within six months of study end
3. Presentations regarding the feasibility study outputs will be submitted to the British Burn Association December 2017 and 2018
4. Dissemination of a lay study report will occur through established routes including the Scar Free Foundation website, burn camps, British Burn Association, Burn Networks and through the project patient champion Pam Warren

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/06/2018		Yes	No
HRA research summary			28/06/2023	No	No