

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

| | | |
|--------------------------|-------------------------------------|--|
| Submission date | Recruitment status | <input type="checkbox"/> Prospectively registered |
| 19/11/2015 | No longer recruiting | <input type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 19/11/2015 | Completed | <input checked="" type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 19/12/2018 | Skin and Connective Tissue Diseases | |

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

Research & Development

Upper Maudlin Street

Bristol

United Kingdom

BS2 8AE

Additional identifiers

Protocol serial number

19367

Study information

Scientific Title

Can Skin grafting success rates in burn patients be improved by using a Low friction 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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

United Kingdom

England

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

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

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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |