ISRCTN61225564 https://doi.org/10.1186/ISRCTN61225564

Study to evaluate pain in split skin graft donor sites dressed with fibrin sealant (Tisseel®, Baxter) and adhesive dressings versus adhesive dressings directly applied to the donor site

Submission date
02/03/2011

Registration date
11/11/2011

Last Edited
06/08/2013

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
GSTT R&D registration number RJ1080009

Study information

Scientific Title

A prospective, controlled, randomised study to evaluate pain in split skin graft donor sites dressed with fibrin sealant (Tisseel®, Baxter) and adhesive dressings versus adhesive dressings directly applied to the donor site

Study objectives
Fibrin sealant significantly reduces pain in split skin graft donor sites

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval obtained from Guys and St Thomas' Ethics Committee on 11th January 2008, ref: 06Q0701/92

Study design
Randomised active control parallel assignment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain in split skin graft donor sites

Interventions
A prospective, randomised controlled trial was performed. The self-adhesive fabric dressing Mefix® (Mölnlycke Health Care Ltd) was used as a control and compared to fibrin glue spray (Tisseel®, Baxter Healthcare Ltd) plus Mefix®.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Daily pain and disability scores from day 1 to 14 post-operatively using a Visual Analogue Scale

Key secondary outcome(s))
1. Length of hospital stay
2. Duration of requirement for dressings

Completion date
31/12/2009

Eligibility

Key inclusion criteria

1. 18 years old and over
2. Conscious during post operative period
3. Small to moderate area of split skin graft (SSG) procedure necessary
4. Lateral thigh SSG donor site preferable

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Hypersensitivity to beef or beef products ((Tisseel® is produced from bovine aprotonin)
2. Those requiring thicker grafts, greater than 8/1000 inch
3. Thigh donor sites unavailable. Back and buttocks can be used as donor sites in certain cases, they may have a different pain profile
4. Known immunodeficiency will have an effect on healing
5. Mental incapacity to consent or undertake questionnaire
6. Concurrently participating in another clinical trial and having received another investigational drug or device within the last 30 days to avoid confounding factors
7. Alternative source of severe distracting pain which may down score donor site pain

Date of first enrolment
11/01/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Consultant Plastic Surgeon
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guys and St Thomas NHS Foundation Trust (UK)

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St Thomas' Hospital (UK) - Plastic Surgery Academic Fund

Results and Publications

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	01/07/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes