

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/11/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/08/2013	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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