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Efficacy of topical diclofenac compared with bupivicaine in autologous split skin graft donor sites

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/07/2012	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr PJH Venn

Contact details
The Queen Victoria Hospital NHS Trust
Holtye Road
East Grinstead
United Kingdom
RH19 3DZ
+44 (0)1342 414000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0190083585

Study information

Scientific Title

Study objectives
Is topical diclofenac more effective than bupivicaine in the treatment of post-operative wound pain at donor site

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Post operative pain

Interventions
Randomised, controlled preliminary study. Patients will act as own control as two separate donor strips will be harvested from different dermatomal distribution.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pain at donor site will be assessed using a visual analogue (VA) scale at 1, 2, 6, 8, 24, 48 and 72 hours post-operatively. Degree of healing will be assessed at dressing changes.

Secondary outcome measures

Not provided at time of registration

Overall study start date
30/03/2004

Completion date
30/03/2005

Eligibility

Key inclusion criteria
Patients over 18 years requiring a split autograft under general anaesthetic

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
30/03/2004

Date of final enrolment
30/03/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

The Queen Victoria Hospital NHS Trust
East Grinstead
United Kingdom
RH19 3DZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Queen Victoria Hospital NHS Trust (UK)

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