

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/07/2012	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 bupivacaine 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