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# A prospective double-blinded randomised controlled trial to assess the efficacy of pre-emptive analgesia in forefoot surgery

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| **Submission date**<br>29/09/2006 | **Recruitment status**<br>Stopped | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>29/09/2006 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>27/09/2011 | **Condition category**<br>Surgery | |

**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**
N0227165434

## Study information

**Scientific Title**

## Study objectives
Does pre-operative administration of ankle block (pre-emptive analgesia) provide better post-operative pain control as compared to post-operative ankle block in patients undergoing bony forefoot surgery under a general anaesthetic?

## 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

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Surgery: Forefoot

## Interventions
Patients meeting the inclusion criteria would be randomised to one of the two groups using a sealed envelope technique.

One group of patients would receive an ankle block using 20ml of 0.25% bupivacaine after they are anaesthetised using a general anaesthetic, 10 minutes before the skin incision. The second group of patients would be administered an ankle block using the same method at the time of wound closure.The patient would be blinded to the type of ankle block.

All the patients would be asked to score their post-operative pain at 4, 8 and 24 hours. The pain would be assessed using linear visual analogue scale. The person assessing the post-operative pain would also be blinded to the type of analgesia. Additional analgesia would be administered on patient's request. This would include 60mg of codeine and 1gm paracetamol. The patients would be asked to note the pain score whenever an analgesic is administered. The time of onset of pain and the frequency of analgesics required would be noted.

Added 27 August 2008: trial stopped due to poor recruitment.

## Intervention Type
Procedure/Surgery

## Phase
Not Specified

## Primary outcome(s)

1. Time of onset of post-operative pain
2. Pain scores at 4, 8 and 24 hours in both groups
3. Requirement of post-operative analgesia

### Key secondary outcome(s))
Not provided at time of registration

### Completion date
30/11/2005

### Reason abandoned (if study stopped)
Poor recruitment

## Eligibility

### Key inclusion criteria
1. Patients undergoing bony forefoot surgery under a general anaesthetic
2. ASA grade 1-2

The sample size has been calculated by Dr Arts

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Not Specified

### Key exclusion criteria
1. Patients with chronic pain problems
2. Patients with peripheral neuropathy
3. Patients needing regular analgesics for other painful conditions
4. Children of the age of 16 or below

### Date of first enrolment
01/05/2005

### Date of final enrolment
30/11/2005

## Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**Ward 34**
Cleveland
United Kingdom
TS4 3BW

# Sponsor information

**Organisation**
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

# Funder(s)

**Funder type**
Government

**Funder Name**
South Tees Hospitals NHS Trust (UK)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration