

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

Submission date 29/09/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/09/2011	Condition category Surgery	<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

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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