ISRCTN47246491 https://doi.org/10.1186/ISRCTN47246491

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr S Patil

Contact details
Ward 34
The James Cook University Hospital
Marton Road
Cleveland
United Kingdom
TS4 3BW
+44
sunitpatil@doctors.org.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2005

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

Age group
Adult

Sex
Not Specified

Target number of participants
40 patients in each group: 80

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
England

United Kingdom

Study participating centre
Ward 34
Cleveland
United Kingdom
TS4 3BW

Sponsor information

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals 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