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Post-operative analgesia for day-case ankle arthroscopy

Submission date	Recruitment status	[ ] Prospectively registered
28/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/09/2016	Surgery	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6718

Study information

Scientific Title
Post-operative analgesia for day-case ankle arthroscopy: comparison of intra-articular racemic (RS)-bupivacaine with S(-)-bupivacaine

Acronym
Bupivacaine study

Study objectives
1. To investigate whether intra-articular S(-)-bupivicaine provides prolonged duration of post-operative analgesia in comparison to racemic (RS)-bupivicaine following ankle arthroscopy
2. To investigate whether intra-articular S(-)-bupivicaine reduces supplemental analgesia requirements in comparison to racemic (RS)-bupivicaine following ankle arthroscopy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brighton East REC, 12/09/2007, ref: 07/Q1907/34

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Anaesthetics

Interventions
Post-operative, single injection of 20 ml of 0.5% S(-)-bupivicaine or 20 ml 0.5% racemic (RS)-bupivicaine into the ankle joint.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bupivicaine

Primary outcome measure
The analgesic effect of treatments:
1. Time to first supplemental analgesia following discharge from recovery
2. Visual Analogue Scale (VAS) at 30 mins, 1 hour

Secondary outcome measures
1. Differences in VAS scores between intra-articular chirocaine and marcain in the first 24 hours
2. Investigate whether intra-articular chirocaine reduces supplemental analgesia requirements in comparison to marcain in the first 24 hours

Overall study start date
29/04/2008

Completion date
01/11/2009

Eligibility

Key inclusion criteria
Patients aged 18 years and above undergoing day case ankle arthroscopy who have given informed written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 84

Key exclusion criteria
1. Allergy or intolerance to any drugs used in the study
2. Spinal or epidural anaesthesia
3. Pregnancy

Date of first enrolment

29/04/2008

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Worthing and Southlands Hospitals
West Sussex
United Kingdom
BN11 2DH

Sponsor information

Organisation
Sussex NHS Research Consortium (UK)

Sponsor details
Research & Development Department
Worthing Hospital
Lyndhurst Road
Worthing
England
United Kingdom
BN11 2DH

Sponsor type
Hospital/treatment centre

Website
http://www.sxrc.nhs.uk/

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories Ltd (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