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Comparison of the potential short and long term benefits of the use of a continuous popliteal nerve block compared to a single shot technique in patients undergoing surgical repair of ankle fractures

Submission date 06/08/2009	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 01/10/2009	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 12/06/2014	**Condition category** Surgery	[ ] Individual participant data [ ] 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
RGHT 000669

Study information

Scientific Title
Comparison of the effects of single or continuous popliteal nerve block on post-operative outcome measures in patients undergoing operative repair of ankle fracture: a randomised controlled double-blind trial

Study objectives
Does the use of a continuous popliteal nerve block after ankle fracture surgery reduce the incidence of chronic post-surgical ankle pain?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee 2 (HSC REC 2) approved on the 28th July 2009 (ref: 09/NIR02/38)

Study design
Randomised double blind controlled 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgical repair of ankle fracture

Interventions
Single shot popliteal nerve block followed by randomisation to receive either a continuous popliteal nerve block using 0.125% levobupivacaine or placebo infusion.

For each patient, in hospital follow up will continue for 48 hours after their surgical procedure. Patients will then be contacted at 3 months post-procedure and asked to fill in a repeat Magill pain questionnaire. This will be the end of the study for this patient.

Added 09/08/2011: Study did not commence due to issues with equipment & funding

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Reduction in the incidence of chronic ankle pain at three months post-procedure

Secondary outcome measures
1. Post-operative morphine usage assessed at designated times in the post-operative period: one hour after surgery before leaving the recovery area and at 4, 8, 12, 16, 24, 30, 36 and 48 hours after the procedure
2. Time to first mobilisation, recorded at time to first mobilisation
3. Difference in pain scores in both the post-operative period and on first mobilisation assessed at designated times in the post-operative period: one hour after surgery before leaving the recovery area and at 4, 8, 12, 16, 24, 30, 36 and 48 hours after the procedure and on first mobilisation
4. Total length of hospital stay, recorded from the day of admission to day of discharge
5. Patient satisfaction assessed at the end of the 48 hour post-operative period using the 40-item quality of recovery (QoR-40) questionnaire

Overall study start date
17/08/2009

Completion date
29/04/2010

Reason abandoned (if study stopped)
Lack of funding/resources

Eligibility

Key inclusion criteria
1. American Society of Anaesthesiologists (ASA) class I - III
2. Patients able to give written informed consent
3. Patients awaiting operative repair of an ankle fracture
4. Aged between 18 - 80 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60 patients divided into two groups of 30

Key exclusion criteria
1. History of an allergy to any of the medications used in the study
2. Pregnancy
3. Local infection at site of nerve blockade
4. Any form of neurological dysfunction in lower limbs
5. Patients suffering from severe hypotension such as cardiogenic or hypovolaemic shock or with a serious cardiac arrhythmia

Date of first enrolment
17/08/2009

Date of final enrolment
29/04/2010

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Department of Anaesthetics & Intensive Care Medicine
Belfast
United Kingdom
BT12 6BJ

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Grosvenor Road
Belfast
Northern Ireland

United Kingdom
BT12 6BA

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net/

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Belfast Health and Social Care Trust (UK) (ref: RGHT 000669)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No