ISRCTN96057529 https://doi.org/10.1186/ISRCTN96057529

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Reduction in the incidence of chronic ankle pain at three months post-procedure

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Northern Ireland

Study participating centre
Department of Anaesthetics & Intensive Care Medicine
Belfast
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Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes