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Additional pain control using Surgically Placed Wound Catheters (SPWC) and local anaesthetic infusion after mastectomy and breast reconstruction

Submission date 06/07/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 25/08/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/05/2018	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-pain-control-after-breast-cancer-surgery

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Additional pain control using Surgically Placed Wound Catheters (SPWC) and local anaesthetic infusion after mastectomy and breast reconstruction a randomized controlled trial

Acronym
SPWC

Study objectives
Usage of surgically placed wound catheter and local anaesthetic infusion will improve pain relief and comfort after breast surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle 2 Ethics committee ref: 11/NE/0131

Primary study design
Interventional

Study design
Type A: Oral and parenteral opioid based analgesia for breakthrough pain
Type B: Oral and parenteral opioid based analgesia for breakthrough pain and in addtion wound catheter placement

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Breast cancer, pain relief, wound catheter, local anaesthetic infusion

Interventions
Surgically placed wound catheter for group B PAJUNK; infiltralong; and local anaesthetic infusion using Ambit; infusion pump and required

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
1. Pain scores (daily and average) following the procedure
2. Total opioid requirements
3. Days opioid free

Key secondary outcome(s)
Side effects of opioid based analgesics such as nausea, drowsiness and constipation

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. Mastectomy alone
2. Mastectomy + sentinel lymph node biopsy (SLNB)
3. Mastectomy + axillary nodes dissection (AND)
4. Mastectomy + reconstruction
5. Reconstruction alone using implant
6. Reconstruction using Latissmus dorsi (LD) flap

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Allergy to local anaesthetic
2. Inability/refusal to perform self assessment
3. Inability to consent due to any reason
4. Has had one of the following procedures:
4.1. All wide local excisions (WLE) and Further WLE
4.2. Only axillary procedure
4.3. Mastopexy as additional procedure
4.4. Readjusting the implants only

Date of first enrolment
01/09/2011

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wansbeck General Hospital
Ashington
United Kingdom
NE63 9JJ

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust (UK)

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Northumbria Healthcare NHS Foundation Trust - Breast Cancer Care Fund (UK)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes