

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/05/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-pain-control-after-breast-cancer-surgery>

Study website

<https://sites.google.com/site/spwctrail/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

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 addition wound catheter placement

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

<https://docs.google.com/viewer?>

[a=v&pid=sites&srcid=ZGVmYXVsdGRvbWFPbnxzczHjdHJpYWx8Z3g6YzU3NjZlNDMwZDU1YTlj](https://docs.google.com/viewer?)

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; infiltral along; 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 measure

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

Secondary outcome measures

Side effects of opioid based analgesics such as nausea, drowsiness and constipation

Overall study start date

01/09/2011

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 Latissimus dorsi (LD) flap

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

100

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

England

United Kingdom

Study participating centre

Wansbeck General Hospital

Ashington

United Kingdom

NE63 9JJ

Sponsor information

Organisation

Northumbria Healthcare NHS Foundation Trust (UK)

Sponsor details

Rake Lane

North Shields

England

United Kingdom

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caroline.potts@NHCT.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.northumbria.nhs.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

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