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SUBpectoral Local anaesthetic Infusion following MastEctomy - version 1 (SUBLIME)

Submission date	Recruitment status	[X] Prospectively registered
05/09/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/09/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/05/2019	Cancer	[_] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-extra-type-pain-control-after-surgery-remove-your-breast-sublime

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-005775-16

Protocol serial number
12964

Study information

Scientific Title
A randomised, double blind, placebo-controlled trial of continuous subpectoral local anaesthetic infusion for pain and shoulder function following mastectomy

Acronym
SUBLIME v1

Study objectives
The aim of the study is to establish whether the use of continuous local anaesthetic infusion in the sub-pectoral tissue plane can improve post-operative analgesia and quality of life for patients undergoing mastectomy with or without axillary surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 06/06/2012, ref: 12/SW/0149

Study design
Randomised interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast Cancer

Interventions
Participants will be randomised to receive 0.25% levobupivacaine or placebo (0.9% saline) by sub-pectoral infusion for 24 hours and will be followed up at 24 hours, 14 days and six months post-operatively.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Total morphine consumption, measured during the first 24 hours post-operatively

Key secondary outcome(s))

Total pain, measured using the Visual Analog Scale for Pain (VAS Pain) in the first 24 hours post-operatively

Completion date
14/08/2016

Eligibility

Key inclusion criteria
1. All women presenting for unilateral mastectomy surgery at the Royal Cornwall Hospitals NHS Trust and Royal Devon and Exeter NHS Foundation Trust
2. Female
3. Aged 18 years and over
4. Scheduled for unilateral mastectomy with or without axillary involvement

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Inability to give informed consent
2. Primary reconstructive surgery
3. Hypotension, hypovolaemia or any form of shock
4. Known allergy or sensitivity to local anaesthetic agents, morphine, paracetamol or ondansetron
5. Pregnancy
6. Daily opioid analgesic use
7. Inability to understand or use a PCA device
8. Inability to understand or complete the visual analogue assessment tools
9. Concurrent participation in another interventional study that might conflict with this trial

Date of first enrolment
06/12/2012

Date of final enrolment
28/07/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Cornwall Hospitals NHS Trust
Truro
United Kingdom
TR1 3LJ

Study participating centre
York Teaching Hospital NHS Foundation Trust
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
Royal Cornwall Hospitals NHS Trust (UK)

ROR
https://ror.org/026xdcm93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (ref: PB-PG-0610-22342)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	30/09/2014		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes