ISRCTN46621916 https://doi.org/10.1186/ISRCTN46621916

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

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

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

EudraCT/CTIS number
2011-005775-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 to request a patient information sheet

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 measure
Total morphine consumption, measured during the first 24 hours post-operatively

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

Overall study start date
15/10/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
UK Sample Size: 160

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
England

United Kingdom

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)

Sponsor details
Treliske
Truro

England
United Kingdom
TR1 3LJ

Sponsor type
Hospital/treatment centre

Website
http://www.rcht.nhs.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

Publication and dissemination plan
To be confirmed at a later date

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?
Protocol article	protocol	30/09/2014		Yes	No
HRA research summary			28/06/2023	No	No