

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

Submission date 05/09/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/09/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/05/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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