

A randomised double-blind placebo-controlled trial of Sub-Pectoral catheter bupivacaine Infusion for post-mastectomy pain

Submission date 01/11/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/04/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/11/2013	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym

SPI-Mas

Study objectives

The primary common complications of mastectomy with axillary node clearance are post-operative pain and slow recovery of shoulder function.

Historically, mastectomy patients are managed on the wards with systemic opiates, either by intramuscular injection or using a Patient Controlled Analgesia (PCA) device. Problems commonly associated with this technique are inadequate pain control, post-operative nausea and vomiting, poor recovery of shoulder function and chronic pain.

We ask the question: can post-operative analgesia be improved in this patient group by the use of local anaesthetic infusion via a sub pectoral catheter?

This prospective, randomised double blind placebo-controlled study of patients undergoing mastectomy plus axillary sampling or clearance for breast cancer aims to investigate whether this technique confers any advantages over current practice.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval will be submitted from the Cornwall NHS Hospitals Local Research and Ethics Committee. Pending as of 06/11/2007.

Study design

A prospective, single-centre, double blind randomised placebo-controlled study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Post-mastectomy pain

Interventions

Local anaesthetic bupivacaine infusion (initial bolus of 20 ml of 0.5% sterile bupivacaine) via a sub-pectoral catheter inserted intra-operatively versus saline control (initial bolus of 20 ml sterile saline 0.9%).

Thereafter continuous drug infusion will be 270 ml of either 0.25% bupivacaine or of 0.9% saline via an elastomeric infusion device delivering 5 ml/hr over 48 hours.

All study arms have same duration. Initial phase of study is for the first 10 days following surgery, the second phase is the follow-up at 6 and 12 months. Total duration will therefore be 12 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bupivacaine

Primary outcome measure

Post-operative analgesia as assessed by:

1. Total morphine requirements at 24 and 48 hours
2. Pain scores at rest on first waking using a Verbal Rating Scale
3. Pain scores at rest and on movement using a Visual Analogue Scale at 24 and 48 hours
4. Time from end of surgery to first analgesia
5. Subsequent oral analgesia (oromorph) requirements

Secondary outcome measures

1. Pain scores at rest and on movement using a Visual Analogue Scale at 10 days, 6 months and 1 year
2. Shoulder function assessment using Oxford Shoulder Score and Shoulder Goniometry at 24 hours, 48 hours, 10 days and 6 months
3. Incidence and severity of nausea and vomiting
4. Requirement for post-operative anti-emetic
5. Surgical complications, e.g., seroma/infection
6. Patient satisfaction at 10 days
7. Analgesia requirements at 6 months
8. Requirement for re-operation due to complication
9. Duration of post-operative hospital stay

Overall study start date

01/01/2008

Completion date

01/06/2009

Eligibility

Key inclusion criteria

Female patients over the age of 18 who are scheduled for elective single side mastectomy with axillary surgery at Royal Cornwall Hospital Trust will be recruited.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

70

Key exclusion criteria

1. Concurrent enrolment in any other study/trial
2. Pregnancy
3. Bilateral surgery
4. Primary reconstructive surgery
5. Known allergy or sensitivity to local anaesthetic agents, morphine, paracetamol or ondansetron
6. Chronic opioid or non-opioid analgesic use
7. Inability to give informed consent
8. Inability to understand or use a patient-controlled analgesia (PCA) device
9. Inability to understand or complete the visual analogue assessment tools

Date of first enrolment

01/01/2008

Date of final enrolment

01/06/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Cornwall Hospital Trust
Truro, Cornwall
United Kingdom
TR1 3LJ

Sponsor information

Organisation

Royal Cornwall Hospital Trust (UK)

Sponsor details

c/o Cathryn Love-Rouse
Senior Manager Research and Development
Research and Development Directorate
Knowledge Spa
Truro
England
United Kingdom
TR1 3HD

Sponsor type

Hospital/treatment centre

Website

<http://www.cornwall.nhs.uk/RCHT/Home.aspx>

ROR

<https://ror.org/026xdc93>

Funder(s)

Funder type

Government

Funder Name

Royal Cornwall Hospital Trust (UK) - NHS clinical trial using existing resources

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