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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/04/2008	**Overall study status** Completed	
Last Edited 18/11/2013	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gail Gillespie

Contact details
Royal Cornwall Hospital Trust
Treliske
Truro, Cornwall
United Kingdom
TR1 3LJ

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 wakening 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/026xdcm93

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