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# Readyfusor health economics study

**Submission date**
26/10/2017

**Recruitment status**
No longer recruiting

**Registration date**
06/11/2017

**Overall study status**
Completed

**Last Edited**
01/04/2019

**Condition category**
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
Although managing pain after surgery has steadily improved, there is still a need to identify the best methods after specific types of surgery, based upon effectiveness, reliability, safety, convenience (for both patients and hospital staff) and costs. This study will compare two types of pain management: epidural analgesia and continuous wound infusion. Epidural analgesia is an injection in the spine that prevents pain and continuous wound infusion uses a catheter to deliver medication. Both of these techniques are already used routinely in the hospital to see if there are any differences to patient care and costs. This study will review pain scores, medication side effects like (sickness or constipation) and ask the patient and the nursing staff for feedback on pain relief methods presently used. The aim of this study is to measure the overall costs of providing analgesia by wound infusion using BioQ ReadyfusOR compared to epidural analgesia.

Who can participate?
Adults aged 18 and older who are scheduled to undergo a laparotomy (the surgical procedure that involves an incision in the abdominal wall).

What does the study involve?
All medical care is done to the standard level of care, including the method of pain management agreed by the patient and anaesthetist (the doctor who provides anaesthesia during operations). On the day of surgery, the consultant anaesthetist discuss the general anaesthetic (being asleep) for the operation, and the combination of ways that pain will be minimised, including the choice between an epidural or 'Readyfusor' wound infusion. In the anaesthetic room, next door to the operating theatre participants receive either the epidural method, the anaesthetist will insert a fine cannula (tube) into the epidural space, and a dose of local anaesthetic is injected, before going off to sleep with the general anaesthetic or the 'Readyfusor' wound infusion method starts after patient has gone off to sleep with the general anaesthetic. Participants receive a simple injection of local anaesthetic, called a 'TAP' block on either side of the abdomen. Thereafter, the general anaesthesia and surgery continue identically and as per routine until the time for closure (stitching up) of the wound to complete the operation. Once the patient returns to the ward and wakes from the operation, pain relief is provided via the epidural infusion or the 'Readyfusor' wound infusion. If pain levels are not comfortable, the patient's pain control is reviewed. The healthcare costs are measured by recording the costs of materials and equipments during all parts of the study.

What are the possible benefits and risks of participating?
As this study follows two standard care pain control methods, the patient may not notice a benefit in participation on the study. Although we hope pain control methods may help the patient recover, this cannot be guaranteed. If the patient feels too uncomfortable, we will as per routine care, provide whatever additional pain treatments are required to ensure that the pain returns to a tolerable level. The information we get from this study will also help us to improve the choice of treatment for future patients having abdominal operations, for which local anaesthetic epidural or wound infusion are recommended methods for pain management in the first 48 hours after surgery. There are some risks including the catheter placement as the participant could potentially experience discomfort at the catheter site (e.g. redness, swelling, or bruising). The drugs used in this study are drugs commonly used in clinical practice. The safety of the doses, methods of administration, and routes of administration have all been proven safe and effective through numerous clinical studies. Potential side effects from rescue medication or analgesia include itching, nausea and vomiting, hypotension, respiratory depression, constipation.

Where is the study run from?
The London Clinic (UK)

When is the study starting and how long is it expected to run for?
October 2016 to December 2018

Who is funding the study?
BioQ Pharma (USA)

Who is the main contact?
Dr Josh Kriesel

# Contact information

### Type(s)
Public

### Contact name
Dr Josh Kriesel

### Contact details
BioQ Pharma
185 Berry Street Suite 160
San Francisco
United States of America
94107

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
IPPS-2017-01

# Study information

### Scientific Title
Pilot healthcare economics and observational study of the OneDose ReadyfusOR (a factory-filled infusion device delivering a continuous infusion of ropivacaine 2mg/ml for up to 48 hours), for the treatment of post-operative pain in patients who have undergone open intra-abdominal surgery (laparotomy)

### Study objectives
The aim of this study is to measure the overall costs of providing analgesia by wound infusion using BioQ ReadyfusOR compared to epidural analgesia.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
London - City & East Research Ethics Committee, 06/09/2017, ref:v 17/LO/0572

### Study design
Prospective open-label observational study

### Primary study design
Observational

### Secondary study design
Case-control study

### Study setting(s)
Hospital

### Study type(s)
Other

### Participant information sheet
See additional files

### Health condition(s) or problem(s) studied
Post-operative pain

### Interventions
The study interventions being compared, are:
1. Epidural analgesia as per the anaesthetist's usual practice and as per hospital protocol. Post-operative infusion will be with one of the three standard solutions of levo-bupivacaine (0.125% plain; 0.1%+ fentanyl 2 mcg/ml; 0.125% + fentanyl 4 mcg/ml) in routine use in TLC.
2. Wound infusion (ropivacaine 2mg/ml i.e. 0.2% at 5ml/hour) via a multi-hole catheter, using the ReadyfusOR. After wound closure at the end of surgery, the catheter will be primed with a bolus dose of ropivacaine 2mg/ml 5ml.

The entire care of the patient (including the multimodal analgesia) is at the discretion of the responsible clinicians, and governed only by TLC usual care and protocols.

Data to determine the healthcare costs is collected during the set-up, administration and up to one week after the epidural or wound analgesic infusions.

The steps are as follows:
Visit 1: Screening, eligibility check:
The consent procedure will be followed. For patients consenting to participate their GP is notified.

Visit 2: Day of Surgery:
Pre-operatively, anaesthetist and patient discuss and re-confirm the analgesic method: epidural or wound infusion. Participants have their baseline demographics and vital signs recorded as per routine in the medical notes. Resource use (medicines, consumables and equipment), staff involved and timing captured in the preparation and delivery of analgesia and treatment of analgesia related side effects in the anaesthetic room and operating theatre. The 48 hour period starts from end of surgery (wound dressings completed) and includes wound infusion commenced/epidural infusion commencing in the Operating theatre/recovery room and having pain related activities timed and concomitant drugs, consumables and equipment recorded including analgesic rescue measures.

Visit 3: Study period 0-24 hours post-surgery
Participants have their pain related activities timed and concomitant drugs, consumables and equipment recorded including analgesic rescue measures. Overnight data is gleaned from patient report (as per routine practice during the daily In-Patient Pain Medicine Ward Rounds), ward nurses' and doctors' verbal reports and notes, the drug prescription charts and observation charts.

Visit 4: Study period 24-48 hours post-surgery
Participants have their pain related activities timed and concomitant drugs, consumables and equipment recorded including analgesic rescue measures – overnight data gleaned from patient report (as per routine practice during the daily In-Patient Pain Medicine Ward Rounds), ward nurses' and doctors' verbal reports and notes, the drug prescription charts and observation charts

Visit 5:
This includes post-study patient and staff questions.

Visits 6 & 7: Post treatment/end of study follow-up:
This is conducted at one and five-seven days post treatment period, in the ward, or if discharged, by telephone assessment, to determine pain scores, analgesia usage, side-effects, wound complications e.g. infection.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Ropivacaine

### Primary outcome measure
Healthcare costs are measured using the health economics items starting with a standardised time for preparation of epidural or TAP block materials (based on timed simulations of each of the two preparations), followed by the real-time data collection commencing from the time of the patient's arrival in the anaesthetic room.

The contributions associated with the pain relief method in relation to staff time and costs of materials and equipment will be collected during the study by recording and timing the members of staff involved in the preparation, before theatre and in-theatre; and catheter placement of post-operative pain relief in-theatre. In the 48hour period post-surgery, contributions in relation to staff time and cost, materials and equipment will be determined from the patient's case notes. The staff time, materials and equipment will be logged in physical units and translated into costs using published unit costs.

### Secondary outcome measures
1. Patient's average daily and worst pain scores is measured using a NRS (0-10) at screening, 24 hours post-surgery, 48 hours post surgery, 7-9 days after surgery (5-7 days post treatment)
2. OneDose ReadyfusOR or epidural attributable or opioid related side-effects or complications recorded by staff. Measurements are recorded when complication occurs and is not limited to time intervals. The complications recorded include, but are not limited to analgesia trouble shooting, accidental disconnections, bag changes, adverse event recording (e.g. nausea, itching, hypotension, respiratory depression, constipation) and rescue drug requirements
3. Total dose in morphine equivalent dosage (MED) for opioid rescue analgesics. Comparisons will be made to documented opioid sparing effects when the OneDose ReadyfusOR is used for the treatment of post-operative pain, or to PCA only patients. Rescue medication is noted at all time intervals when medication was required. Measurements include rescue drug name, drug dose, frequency of medication, route of administration, start and stop date and time, additional equipment required for treatment, staff involved in intervention, and reported time taken to administer medication.
4. The patients' evaluations of impact on mobility is measured using a patient satisfaction questionnaire with responses recorded based on numerical scale (0-10), where 0 indicates pain does not interfere or prevent the patient from performing specific activities, and 10 indicates that pain completely interferes at 24 hours post-surgery, 48 hours post surgery, 7-9 days after surgery (5-7 days post treatment)
5. Staff members' evaluations of ease-of-use and impact on mobility is measured using a patient satisfaction questionnaire with responses recorded based on numerical scale (0-10) at 24 hours post-surgery, 48 hours post surgery, 7-9 days after surgery (5-7 days post treatment

### Overall study start date
19/10/2016

### Completion date
31/03/2020

## Eligibility

### Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 18 years or above
3. Adult patients ≥ 18 years of age scheduled to undergo a laparotomy

4. Able (in the Investigators opinion) and willing to comply with all study requirements
5. Able to understand and provide signed informed consent, and to answer the study related questions
6. Normally active, and judged to be in stable health (ASA I-III: Healthy person; or mild or stable systemic disease) on the basis of routine pre-surgery assessment: medical history, physical examination and standard care investigations
7. Female participants of child bearing potential and male participants whose partner is of child bearing potential must be willing to ensure that they or their partner use effective contraception during the study and for 3 months thereafter
8. Participant has clinically acceptable laboratory and ECG findings
9. Willing to allow his or her General Practitioner (GP) and consultant, if appropriate, to be notified of participation in the study

## Participant type(s)
Healthy volunteer

## Age group
Adult

## Lower age limit
18 Years

## Sex
Both

## Target number of participants
20

## Key exclusion criteria
1. Female participant who is pregnant, or lactating, during the course of the study
2. History of allergy to study related drugs, which would preclude all of the possible combinations, capable of providing usual care multimodal analgesia: other local anaesthetics, morphine, oxycodone, fentanyl, paracetamol
3. Significant renal or hepatic impairment
4. Clinically significant illness or surgery within 1 week prior to screening visit (including flu, flu like symptoms, diarrhea, vomiting, ongoing sepsis/bacterial infections)
5. Clinically significant ECG abnormalities or vital sign abnormalities (systolic blood pressure lower than 90 or over 160 mmHg, diastolic blood pressure lower than 40 or over 90 mmHg, or heart rate less than 50 or over 100 bpm) at screening.
6. Chronic pain, with or without long-term regular analgesic usage
7. History of substance abuse
8. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant’s ability to participate in the study
9. Participants who have participated in another research study involving an investigational product in the past 12 weeks.
10. Current or recent (in the last 30 days) inclusion in another research study.

NOTE: If the patient has a history of allergy to ropivicaine, but is known to tolerate laevo-bupivicaine, then epidural analgesia remains a viable option, if deemed acceptable by the patient and anaesthetist. They will not be eligible for treatment with the RF, which contains ropivicaine.

### Date of first enrolment
15/11/2017

### Date of final enrolment
31/01/2020

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**The London Clinic**
London
United Kingdom
W1G 6BW

## Sponsor information

### Organisation
BioQ Pharma

### Sponsor details
185 Berry Street Suite 160
San Francisco
United States of America
94107

### Sponsor type
Industry

## Funder(s)

### Funder type
Industry

**Funder Name**
BioQ Pharma

# Results and Publications

### Publication and dissemination plan
Planned publication in a high impact peer review journal.

### Intention to publish date
31/03/2021

### Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version V3 | 16/10/2017 | 01/04/2019 | No | Yes |
| HRA research summary | | | 28/06/2023 | No | No |