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# Treatment of pain following keyhole surgery in West Africa

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 27/06/2018 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 03/07/2018 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 09/08/2019 | Surgery | |

## Plain English summary of protocol

Background and study aims
Following keyhole surgery patients often experience significant pain and this can delay their return to their normal activities. Some surgeons inject local anaesthetic at the end of the operation into the parts of the abdomen where cuts were made, in order to reduce pain over the first few postoperative hours. However there is no good evidence to support this practice in Nigeria and a large trial is needed to test whether these local anaesthetic injections do reduce pain. The aim of this initial, small study is to find out whether it is possible to run a large-scale randomised study to address this research question in Nigeria.

Who can participate?
Adult patients (18 years or older) undergoing planned keyhole (laparoscopic) surgery for removal of the gallbladder.

What does the study involve?
All participants will receive an injection at the keyhole cut sites. Participants will be randomly allocated to receive either one of two local anaesthetics in the injections, or sterile salt water (saline) only. At four points in the 24 hours following surgery, participants' pain and nausea will be assessed by a doctor asking simple questions.

What are the possible benefits and risks of participating?
Patients who receive a local anaesthetic reaction may experience better pain control. There is a very low risk of an allergic reaction to the injections administered.

Where is the study being run?
Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Nigeria

When is the study starting and how long is it expected to run for?
July 2015 to June 2017

Who is the main contact?
Dr Adewale O. Adisa, wadisc@yahoo.com

# Contact information

### Type(s)
Public

### Contact name
Dr Adewale Adisa

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Department of Surgery, Obafemi Awolowo University
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
-

# Study information

### Scientific Title
Feasibility study for a randomised controlled trial of bupivacaine, lignocaine with adrenaline, or placebo wound infiltration to reduce postoperative pain after laparoscopic cholecystectomy in West Africa

### Study objectives
This trial was designed to determine the benefits of local anaesthetic (bupivacaine or lignocaine with adrenaline) port site infiltration to reduce pain. We aimed to deliver this external feasibility study to determine whether a full phase randomised trial could be delivered.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics and Research Committee of the Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Nigeria, May 2015, IRB/IEC/0004553

### Study design
Feasibility randomised controlled trial

### Primary study design
Interventional

## Secondary study design
Randomised parallel trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
See additional files

## Health condition(s) or problem(s) studied
Pain following laparoscopic cholecystectomy

## Interventions
At the end of the procedure, skin, subcutaneous tissue, fascia, and parietal peritoneum will be infiltrated with one of the following solutions:
1. 3 ml of 2% lignocaine with adrenaline in each 10-mm port site and 2 ml in each 5-mm port site (total 200 mg of lignocaine with 1:1000 adrenaline)
2. 3 ml of 0.5% bupivacaine hydrochloride (Marcaine® 0.5%) in each 10-mm port sites and 2 ml in each 5-mm port site (total 50 mg of plain bupivacaine)
3. 3 ml of 0.9% saline in each 10-mm port site and 2 ml in each 5-mm port site.

## Intervention Type
Drug

## Phase
Phase II

## Drug/device/biological/vaccine name(s)
Bupivacaine, lignocaine with adrenaline

## Primary outcome measure
1. Number of patients recruited over a 24 month period
2. Compliance with randomised treatment allocation assessed by the proportion of patients who receive their randomised treatment allocation
3. Outcome assessment completion assessed by the proportion of pain assessments (measured using both the numerical rating scale and verbal rating scale at 2, 6, 12, and 24 hours postoperatively) and nausea assessments (measured using the numerical rating scale measured at 2, 6, 12, and 24 hours postoperatively) that are completed

## Secondary outcome measures
Completion of nausea assessment (numerical rating scale) at 2, 6, 12, and 24 hours postoperatively,

## Overall study start date
15/10/2014

## Completion date

30/04/2018

# Eligibility

### Key inclusion criteria
1. Aged 18 years or older
2. Undergoing elective laparoscopic cholecystectomy for symptomatic gallstone disease

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
69

### Key exclusion criteria
1. American Society of Anesthesiology (ASA) physical status class 3+
2. Pregnant women
3. Acute cholecystitis
4. History of allergy to bupivacaine, lignocaine or related local anaesthetic drugs
4. Known peptic ulcer disease
5. Known opiate addiction
6. Known contraindications to use of NSAIDs such as bronchial asthma
7. If an abdominal drain is inserted or the operation was converted to an open procedure, the patient will not receive the allocated intervention and pain scores will not be collected

### Date of first enrolment
01/07/2015

### Date of final enrolment
30/06/2017

# Locations

### Countries of recruitment
Nigeria

### Study participating centre
**Obafemi Awolowo University Teaching Hospitals Complex**
Ilesa Road

Ile-Ife
Nigeria
220005

# Sponsor information

**Organisation**
Obafemi Awolowo University

**Sponsor details**
P.M.B. 13
Ile-Ife
Nigeria
220282

**Sponsor type**
University/education

**Website**
https://www.oauife.edu.ng

**ROR**
https://ror.org/04snhqa82

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Publication and dissemination plan**
Publication is anticipated in an international surgical journal.

**Intention to publish date**
01/09/2018

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available as this is a feasibility study designed to inform future trial development, rather than to produce clinical data for the evaluation of specific interventions. However, should a legitimate need arise for the dataset, it will be available upon request.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | | 03/07/2018 | 02/04/2019 | No | Yes |
| Results article | results | 26/03/2019 | 04/04/2019 | Yes | No |