ISRCTN17667918 https://doi.org/10.1186/ISRCTN17667918

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
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Additional identifiers

Protocol serial number
-

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
Completion of nausea assessment (numerical rating scale) at 2, 6, 12, and 24 hours postoperatively,

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

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

ROR
https://ror.org/04snhqa82

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

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?
Results article	results	26/03/2019	04/04/2019	Yes	No
Participant information sheet	Participant information sheet	03/07/2018	02/04/2019	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes