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Conventional versus keyhole removal of appendix in Nigerian patients

Submission date
07/09/2022

Recruitment status
No longer recruiting

Registration date
02/11/2022

Overall study status
Completed

Last Edited
02/11/2022

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
We are not sure how much money patients spend on different kinds of operation. This makes it difficult to advise the government and policy makers on investment and spending for healthcare. This study will calculate the amount spent by patients on two types of operation to help with planning for healthcare financing

Who can participate?
Patients who are undergoing operations for removal of the appendix

What does the study involve?
Patients will have their operations done in the usual fashion decided by their surgeon and their hospital. Data regarding their operation, recovery and recuperation will be collected without disclosing the patient's identity. The researchers will also ask specific questions regarding costs incurred by patients. Patients will be followed up till 30 days after the operation.

What are the possible benefits and risks of participating?
The findings will be communicated to surgeons, hospitals, government and policy makers, not only in Nigeria but across the world. This will influence the policies on surgical operations in Nigeria and other countries. Apart from the time to answer the questions, the researchers will not require anything else from participants. Participation in this study will be at no risk to the patient

Where is the study run from?
Obafemi Awolowo University (Nigeria)

When is the study starting and how long is it expected to run for?
January 2022 to January 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Adewale Adisa, ao.adisa@oauife.edu.ng

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
NHREC/01/01/2007- 11/03/2022

Study information

Scientific Title
Outcomes-focused comparison of laparoscopic and open appendectomy in Nigeria: a multicenter cohort study

Acronym
LOAN

Study objectives
There are no significant differences in the outcome of patients with appendectomy operated either by the laparoscopic or open approach across many Nigerian hospitals

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 03/06/2022, National Health Research Ethics Committee of Nigeria (Department of Health Planning, Research & Statistics, Federal Ministry of Health, 11th Floor, Federal Secretariat Complex Phase III, Ahmadu Bello Way, Abuja, Nigeria; +234 (0)9 523 8367; chairman@nhrec.net, secretary@nhrec.net, deskofficer@nhrec.net), ref: NHREC/01/01/2007-03/06/2022

Primary study design
Observational

Study design
Outcomes-focused multicenter cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Uncomplicated acute appendicitis

Interventions
All patients scheduled for appendectomy who consent to the study will be recruited. One arm is treated by laparoscopic appendicectomy while the other arm is treated by open appendicectomy. They will have their operations done in the usual fashion decided by their surgeon and their hospital. Data regarding their operation, recovery and recuperation will be prospectively collected. Patients will be followed up till 30 days after operation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Complications measured using the Clavien-Dindo scale at 30 days after the operation

Key secondary outcome(s)
1. Postoperative length of stay measured as the total number of days spent from the conclusion of operation calculated at the time decision to discharge home is made by a surgeon of sufficient authority
2. Return to normal activities defined as the first-day patients went to work, school, or engaged in the full retinue of premorbid activities (in its broadest sense) after discharge from the hospital
3. Overall cost of operation in Nigerian Naira calculated and reported by the patient, parents, or guardian on day 30 after the operation

Completion date
31/01/2024

Eligibility

Key inclusion criteria
1. All consenting adults and children of all ages with clinical diagnoses of uncomplicated acute appendicitis. Both elective and emergency appendectomies will be recruited.
2. Patients must provide written informed consent for the operation as per the hospital protocol. Consent for this study will largely be for the inclusion of the patients' data in the study

as well as for follow-up for a minimum of 30 days postoperatively. This consent can be obtained in written or verbal forms. Patients' right to decline inclusion and or to withdraw from the study at any point must be ensured and this should not interfere in any way with their surgical care.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
Complicated acute appendicitis

Date of first enrolment
01/07/2022

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Nigeria

Study participating centre
Obafemi Awolowo University Teaching Hospitals Complex
Ile-Ife
Nigeria
220005

Study participating centre
University of Lagos
Idi-Araba
Lagos
Nigeria
100254

Study participating centre

University of Benin Teaching Hospital
Benin City
Nigeria
300001

Study participating centre
National Hospital
Abuja
Nigeria
900211

Study participating centre
Federal Medical Center
Lokoja
Nigeria
260101

Study participating centre
Olabisi Onabanjo University Teaching Hospital
Sagamu
Nigeria
110271

Study participating centre
University of Ilorin Teaching Hospital
Ilorin
Nigeria
240101

Sponsor information

Organisation
Obafemi Awolowo University

ROR
https://ror.org/04snhqa82

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
IPD will be saved on a personal computer dedicated to the trial and will not be publicly available. Data will only be available to hospital leads and data scientists. Each participating center is currently storing data in an Excel spreadsheet. The researchers however desire to keep their records on the RedCap site after securing funding for the study.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			21/09/2022	No	Yes